NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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FEDERAL REGISTER

Vol. 81 Thursday,
No. 126 June 30, 2016

Pages 42453–42982

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Parts 400, 402, 407, and 457

[Docket No. FCIC–14–0005]

RIN 0563–AC43

General Administrative Regulations; Catastrophic Risk Protection Endorsement; Area Risk Protection Insurance Regulations; and the Common Crop Insurance Regulations, Basic Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) finalizes the General Administrative Regulations—Ineligibility for Programs under the Federal Crop Insurance Act, the Catastrophic Risk Protection Endorsement, the Area Risk Protection Insurance Regulations, and the Common Crop Insurance Regulations, Basic Provisions to revise those provisions affected by changes mandated by the Agricultural Act of 2014 (commonly referred to as the 2014 Farm Bill), enacted on February 7, 2014.

DATES: This rule is effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Tim Hoffmann, Director, Product Management, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, Room 421, P.O. Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Background

This rule finalizes changes to the General Administrative Regulations—Ineligibility for Programs under the Federal Crop Insurance Act, the Catastrophic Risk Protection Endorsement, the Area Risk Protection Insurance Regulations, and the Common Crop Insurance Regulations, Basic Provisions that were published by FCIC on July 1, 2014, as a notice of interim rulemaking in the **Federal Register** at 79 FR 37155–37166. The public was afforded 60 days to submit written comments and opinions.

A total of 364 comments were received from 74 commenters. The commenters included persons or entities from the following categories: Academic, farmer, financial, insurance company, producer group, trade association, and other.

FCIC received a number of comments regarding sections of the Farm Bill that were not included in the interim rule. The comments received included but are not limited to (1) section 1404 participation of dairy operations in margin protection program; (2) section 11003 supplemental coverage option; (3) section 11017 stacked income protection plan for producers of upland cotton; (4) section 11022 whole farm diversified risk management insurance plan; and (5) section 11023 crop insurance for organic crops. These sections of the Farm Bill were not a part of this regulation. Therefore, FCIC is not publishing these comments in this final rule. FCIC thanks the public for their input.

The public comments received are organized below by the issues identified in this rule and the specific public comments received. The comments received and FCIC's responses are as follows:

General

Comment: A commenter stated programs to educate farmers on the new provisions contained in the Farm Bill are essential to proper implementation of this legislation and to the long-term success of Northeast agriculture.

The commenter suggested the United States Department of Agriculture (USDA) aggressively promote educational and informational programming, especially initiatives that involve and combine the efforts of public, private and educational entities.

Response: FCIC collaborated with producers, producers groups, agents, approved insurance providers, as well as the National Resource and Conservation Service (NRCS) and the Farm Service Agency (FSA) regarding several sections of the 2014 Farm Bill through meetings, teleconferences, webinars, and listening sessions to develop policies and procedures. The purpose of this outreach was to provide feedback and explain revisions, explain the rationale and approach for implementation, and reach out to specialty groups. General updates to ongoing activities were provided to approved insurance providers. Conservation compliance education included producers, producer groups, agents, and approved insurance provider meetings, collaborations with RMA, NRCS, and FSA, revising forms and certification policy and procedure, as well as providing this information to producers. FCIC conducted 135 in-person and webinar training sessions, and conducted radio spots and other forms of interviews reaching an even larger audience.

FCIC has published information on its Web site highlighting the major changes to the Federal crop insurance program in response to the 2014 Farm Bill implementation. Also published on the Web site are Fact Sheets, Question and Answers, and brochures regarding each section of the Farm Bill. FCIC has worked closely with approved insurance providers to make system changes and prepare procedural documents. In addition, FCIC participated with approved insurance providers and an insurance trade association to train the trainers, underwriters, loss adjusters, and agents. FCIC will continue to promote and educate on the implementation of the Farm Bill provisions as opportunities arise.

Comment: A commenter stated the current agricultural subsidy system is a maze of market distorting and highly parochial policies that generally rewards a handful of large farm businesses or well-connected industry segments at the expense of taxpayers. The system results in costly inefficiencies that detract from program goals and produce numerous unintended consequences. The Federal government bears a disproportionate amount of the financial risks for agribusinesses to the detriment of taxpayers, consumers, and agriculture as a sector making it less competitive, less resilient, and less accountable for its impacts.

The commenter has long advocated for reforms to make the agricultural safety net more cost-effective, transparent, accountable to taxpayers, and responsive to current market conditions and needs. While the Agricultural Act of 2014 fails to take the necessary steps to achieve this reformed safety net, instead of expanding the role of Washington in agriculture through new business income entitlement programs and increasing spending on federally subsidized crop insurance, there is an opportunity to make progress in the implementation of crop insurance provisions.

The commenter strongly encouraged FCIC to remember that while USDA may consider producers and other agricultural businesses "clients," it is taxpayers who are footing the bill. Farm Bills are notorious for vastly exceeding their estimated costs—the last two Farm Bills are on pace to exceed by $400 billion their Congressional Budget Office scores at passage. The decisions FCIC makes in developing and administering programs under its jurisdiction play an important role in determining whether taxpayer-funded agricultural programs will continue to be vastly over budget.

The commenter strongly encourages FCIC to implement the Agricultural Act of 2014 while being cognizant of the reality that federal taxpayers are responsible for more than $17 trillion in debt and are facing annual deficits exceeding $500 billion. The commenter suggested FCIC not simply attempt to maximize spending, but follow the will of Congress in prioritizing federal support only where necessary and in a manner that is cost-effective and transparent.

Response: FCIC does not have the authority to change the amount of subsidies that are mandated by the Federal Crop Insurance Act and such subsidies cannot be eliminated without a change in law by Congress. Since the program changes contained in this rule were mandated by the 2014 Farm Bill, FCIC is required by law to implement the changes and will do so in the most cost-effective and transparent manner possible. No change has been made.

Comment: A commenter stated the third paragraph of background item i. indicates that as of the publication of FR Doc. 2013–25321 on October 25, 2013, a 1971 amendment to the Administrative Procedures Act that previously required codified Federal crop insurance policies to be published for public review and comment is no longer in effect. The commenter believed it would be a loss to FCIC if approved insurance providers, producers and others outside the Federal government were no longer able to ask questions and offer comments to planned policy revisions. Furthermore, the publication of comments and responses in the final rule clarifies the reason for policy changes and helps to avoid potential disputes and ambiguity in policy language. The commenter urged FCIC to continue its practice of publishing all codified crop insurance policy changes in the **Federal Register** for public review and comment.

Response: FCIC is no longer required by the Administrative Procedures Act due to the revocation of the Hardin Memorandum (78 FR 33045) to publish proposed rules because contracts are exempt from notice and comment rulemaking and the crop insurance policy is a contract. FCIC now has the discretion to determine the appropriateness of affording the public an opportunity for notice and comment when promulgating regulations relating to contracts. When issuing rules regarding crop insurance policies in the future, FCIC will take many factors into consideration including but not limited to the nature of the change, and whether it is anticipated to be controversial to any party, the exigency of the change, the significance of the change to stakeholders and any recommendations made by producers, producer groups, agents, loss adjusters, approved insurance providers or other interested parties. To the extent practicable, FCIC will solicit comments before making administrative rules effective, all other rules will be final rule with comment, which still affords the opportunity for the public to comment while making the rule effective upon publication. FCIC may consider the comments received and may conduct additional rulemaking based on those comments.

Comment: A commenter stated throughout section 6 of the CAT Endorsement, FCIC uses the word "paragraph" to reference other portions of the Endorsement, the commenter recommended FCIC replace the word "paragraph" with the word "section." The commenter believed this change will ensure the CAT Endorsement would be consistent with phrasing used in the CCIP Basic Provisions and other crop insurance policies.

Response: FCIC agrees and has made the change accordingly.

Comment: A commenter stated the phrase ". . . within 30 days after you have been billed . . ." in revised section 6(b) of the CAT Endorsement implies the payment must be received within 30 days, precluding any potential for interest owed and making the timeframe for policy termination for unpaid premium ambiguous. As written, this phrase in the CAT Endorsement is inconsistent with the Annual Premium and Administrative Fees section in the applicable Basic Provisions. The commenter therefore recommended FCIC revise section 6(b) as follows: "In return for catastrophic risk protection coverage, you must pay an administrative fee and any applicable premium as specified in paragraph (f) of this section to us, unless otherwise authorized in the Federal Crop Insurance Act;" and insert a new subclause 6(b)(3) that states "You will be billed for any applicable premium and administrative fee not earlier than the premium billing date specified in the Special Provisions."

Response: The phrase "within 30 days after you have been billed" in section 6(b) of the CAT Endorsement was not a change made by the interim final rule. The only change made to section 6(b) of the CAT Endorsement by the interim final rule was to add the phrase "and premium as specified in paragraph (f) of this section" between the phrases "administrative fee" and "to us within." The addition of the phrase "and premium as specified in paragraph (f) of this section" does not preclude the potential for interest owed, when applicable, nor change the termination date of the policy. FCIC disagrees that the addition of the phrase "and premium as specified in paragraph (f) of this section" or the existing phrase "within 30 days after you have been billed" are inconsistent with the provisions in the Annual Premium and Administrative Fees section of the applicable Basic Provisions. However, as provided in the applicable Basic Provisions, if a conflict exists between the CAT Endorsement and the Basic Provisions, the CAT Endorsement controls. No change has been made.

Section 2611

Comment: A commenter did not think crop insurance should be connected with conservation. Farmers should be left alone to maintain their own land. The farmers are paying for their land, not the Federal Government. Farmers know and understand their land much better than USDA or Natural Resources Conservation Service (NRCS). USDA or NRCS cannot even understand the land classifications and want to make all land in a parcel "highly erodible" when there may be only a very small part of the parcel that is really erodible. The commenter recommended FCIC disconnect insurance from NRCS and let insurance companies compete for the business rather than continue with the current monopoly.

The commenter felt we have gotten very far off-base with government programs. The commenter explained that there are so many people working in government now that don't have any real understanding of how to work land, improve it, etc. They are only there to draw a salary and pretend to know something. Let the real farmers and ranchers control agriculture. Government programs now are really created and maintained for special interest groups, and that creates all kinds of requirements for the real farmers who know what they are doing. The people who farm small operations do not have a chance because there is somebody telling them they must do what the government wants when the government is unfairly operated in favor of takers rather than producers. The further we go into government control of farming, the less productivity we will have, and our food costs will continue to sky-rocket.

The commenter recommended separating the Supplemental Nutrition Assistance Program (SNAP) from farm programs. SNAP is leading the country in the wrong direction—dependency on somebody else to provide for those who will not keep a job, or maybe choose to have children with no intention of making a living for them.

Response: The 2014 Farm Bill linked the conservation compliance provisions to eligibility for Federal crop insurance premium subsidy. FCIC is required to implement these provisions of the 2014 Farm Bill. Further, FCIC has no control over how the conservation compliance programs are administered or the designation of highly erodible land. All such decisions are made by FSA and NRCS and communicated to FCIC. However, a producer may obtain Federally reinsured crop insurance without being in compliance with the conservation compliance provisions but such producer will be ineligible for premium subsidy on all Federally reinsured crop insurance policies and plans of insurance. The interim rule did not address any provisions of SNAP. Therefore, the comments cannot be considered in this final rule. No change has been made.

Comment: A commenter stated specialty crop and perennial producers have had limited participation in USDA programs, with the exception of the Federal crop insurance program. This agricultural segment is significant in number of producers and overall production throughout the Northeast and will have the greatest challenge meeting the timeline provided by USDA to comply with the conservation compliance requirements. The commenter requested that USDA recognize this challenge and provide leniency in the form of additional time for specialty crop producers that do not currently have an established relationship with FSA and the NRCS.

Response: The 2014 Farm Bill requires that all persons seeking eligibility for Federal crop insurance premium subsidy must provide a certification of compliance with the conservation compliance provisions beginning with the first full reinsurance year following February 7, 2014. The 2014 Farm Bill also requires that existing processes and procedures be used for certifying compliance to avoid creating an additional burden on producers and to provide fair and equal treatment to all producers regardless of what crops a producer grows or which program benefits a producer is seeking to obtain. Form AD–1026 has been used by producers to certify compliance with the provisions since the 1980's, including specialty and perennial crop producers seeking FSA benefits under programs such as the Tree Assistance Program and multiple *ad hoc* disaster programs.

However, while all persons must file a certification of compliance, Form AD–1026, by June 1, 2015, to be eligible for Federal crop insurance premium subsidy for the 2016 reinsurance year (July 1, 2015—June 30, 2016), the 2014 Farm Bill does provide additional time for producers who are subject to the conservation compliance provisions for the first time to develop and comply with a conservation plan or remedy a wetland violation, if needed. Since the conservation provisions are administered by FSA and NRCS, the terms and conditions relating to the additional time frames are specified in 7 CFR part 12. In addition, producers who are subject to the conservation compliance provisions for the first time will receive priority for NRCS technical assistance in developing and applying a conservation plan or in making a wetland determination, if needed.

Comment: A commenter stated the interim rule states, "Section 2611 of the 2014 Farm Bill links the eligibility for premium subsidy paid by FCIC to an insured's compliance with the Highly Erodible Land Conservation (HELC) and Wetland Conservation (WC) provisions of the Food Security Act of 1985." The premise of these accountability standards—"conservation compliance"—is that receipt of Federal funding is a two-way street, and subsidies should not be used to tear up sensitive land, drain wetlands, or shift unintended costs onto others. These Farm Bill provisions reduce the cost of agricultural pollution and limit long term liabilities by ensuring producers minimize soil erosion on highly erodible land and forgo draining wetlands.

The commenter added that in order for these provisions to be effective, adequate enforcement of these minimum conservation practices must be prioritized after implementation. Independent analysts including USDA's own Office of Inspector General (OIG) found that from 1991 to 2008, compliance with conservation accountability standards varied from region to region, many farms were out of compliance (up to 20 percent in the 1995 OIG report), and millions in taxpayer dollars could have been saved if subsidies were appropriately withheld for risky production practices (*http://www.agri-pulse.com/uploaded/ConservationCompliance.pdf*). Strong enforcement, proper monitoring, and effective implementation should be prioritized so these provisions achieve measurable public benefits. Adequate resources must also be provided to local officials for monitoring and enforcement efforts, and staff members must be well-trained to ensure consistent enforcement from county to county and state to state.

The commenter also suggested that flexibility should also be built into program regulations so local, on-the-ground knowledge and realities are considered in farms' conservation plans. For instance, if only a small portion of a field is categorized as highly-erodible land, the sensitive acres may require a different conservation plan than the rest of the field. In addition, conservation practices should be evaluated in a holistic view to ensure that those with public benefits greatly outweigh others with potential negative impacts. For instance, installing stream buffers to conserve soil and water could be zeroed out if they are covered in excess agricultural residue left over from flooding or heavy rains. Public benefits of conservation practices may also be reduced when drainage tile is installed on farmland, increasing the rate at which water flows from farmland to nearby waterways. Considering these factors when developing conservation accountability standards will ensure that these provisions not only achieve their stated outcomes but also reduce long-term liabilities of agricultural runoff.

Response: Technical determinations regarding the conservation compliance provisions, such as whether land is highly erodible or a wetland, are made by NRCS. NRCS is also responsible for approving conservation and mitigation plans, when needed, to ensure land meets the conservation compliance requirements. The interim rule did not address the development, approval, or enforcement of the technical requirements for conservation or mitigation plans or the associated staffing needs. No change has been made.

Comment: A commenter believed that the conservation compliance provisions from the 2014 Farm Bill are effectively included in the rule concerning the CAT Endorsement, ARPI, and CCIP Basic Provisions. The commenter noted that the same text is included under each of these three parts of the rule. However, there are a few areas where some refinement could be helpful.

The rule specifically denies the premium subsidy for a compliance violation or failure to file a form AD–1026, and then specifically states that failure by the person to pay the full premium (without the premium subsidy) would result in termination of the policy and all other policies with FCIC. For example, section 6(f) of the CAT Endorsement denies the premium subsidy in the case of a violation and section 6(h) terminates the policy for failure to pay the required premium. The commenter supported the way that compliance has been handled in the rule, and the way it has provided clarity to the way FCIC will be handling it.

However, the commenter also pointed out that form AD–1026, as revised in June 2014 by FSA, can represent a somewhat more complex form for producers that are newly covered by compliance requirements—most of which have been participants in crop insurance, but not other USDA programs that have required compliance for some time. This final rule should provide some greater explanation about the form AD–1026, such as indicating the explanatory purpose of the appendix (as expanded in June of 2014), some description of the boxes to be checked on the form, and the significance of the affiliated person section.

The commenter recommended that the final rule include a specific discussion, perhaps in the background section, that indicates the time allowance for development and compliance with an approved conservation plan. The statute specified that any person newly covered would have five reinsurance years and persons that would have been in violation if they had continued participation in the programs requiring compliance would have two reinsurance years to come into compliance. Some indication of this phase in period would be helpful for those producers that are not familiar with conservation compliance requirements. This is especially important since the rule (and the statute) refer to reinsurance year whereas the form AD–1026 refers to crop year. While the commenter agreed with the time allowance and certain other provisions affecting a decision concerning compliance or a violation being left up to FSA, some greater explanation to that effect and perhaps a link to the FSA rules on HELC and WC would be helpful. Even with the reference to FSA responsibilities, the commenter urged FCIC to provide some clarity on the time allowance the insured has for developing and complying with conservation plans where applicable.

The commenter agreed with the clarity provided by the specific reference in the rule background that the HELC and WC provisions apply only to annually tilled crops.

Response: Form AD–1026 is an FSA form used by producers to self-certify compliance with the conservation compliance provisions. On June 30, 2014, FSA released a modified Form AD–1026 and appendix to incorporate the 2014 Farm Bill provisions relating to crop insurance. As an FSA form, the explanation of and instructions for completing the form are provided by FSA, which can be found at *http://forms.sc.egov.usda.gov/efcommon/eFileServices/eForms/AD1026.PDF.* Since it is FSA that is administering the AD–1026 process, it is best that FSA explain the process and the forms to producers and that such information is contained in their procedures where it can be more comprehensive and up to date than FCIC can provide in this rule.

The interim rule changed the applicable crop insurance Basic Provisions to indicate that producers must have Form AD–1026 on file and they must be in compliance with the conservation compliance provisions of 7 CFR part 12. FSA and NRCS administer the conservation compliance programs and make determinations regarding the additional time frames. Therefore, FSA and NRCS are in the best position to explain the requirements to producers regarding the additional time frames to come into compliance with the conservation compliance provisions. The provisions of 7 CFR part 12 regarding the requirements for conservation compliance and the additional time frames for producers who have never participated in programs for which the conservation compliance provisions were applicable to come into compliance can be found at *http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09599.pdf.* However, RMA, FSA, and NRCS have been working diligently to assure that all producers are aware of their obligations under the conservation compliance provisions through meetings, mailings, outreach, etc. To clarify, a producer must provide an AD–1026 form that encompasses all acreage in the producers' farming operation. However, if the crop on acreage does not qualify as an "agricultural commodity" as defined in section 2601 of the Food Security Act of 1985, then the producer may be exempt from the other conservation compliance requirements. No change has been made.

Comment: A commenter stated as USDA implements the new conservation compliance provisions that link compliance to crop insurance, the commenter asked that FCIC take into consideration the impact of access and availability of crop insurance for producers. Close to 80 percent of the nation's wheat acres are covered by crop insurance and the impact of the regulations USDA is developing could have a significant adverse impact on wheat growers' access to crop insurance in future years. The ability of USDA personnel to address highly erodible land (HEL) and wetland compliance issues in the field and work with producers directly on mitigation and understanding of the new requirements will be critical to producers livelihoods.

Specifically, the commenter asked that USDA clarify that producers must only complete the AD–1026 prior to June 1, 2015, not that a completed compliance check be undertaken. It is also very important that USDA ensure that producers undergoing existing wetland compliance review or appeals are not adversely impacted when seeking crop insurance next year.

The 2014 Farm Bill establishes a new date of February 7, 2014 for wetland conversion related to eligibility for crop insurance premium subsidies and wheat growers suggest a clear distinction be made between reviews to determine eligibility for premium subsidies for crop insurance, and participation in agriculture risk coverage (ARC) or price loss coverage (PLC) and conservation programs. The 2014 Farm Bill also establishes timeframes for producers to come into compliance if they have not been participating in programs covered by conservation compliance. There are wheat growers who may not currently be participating in commodity or conservation programs, and are, therefore, not subject to conservation compliance, so they may need to use the time to come into compliance. USDA must ensure that these producers needing to come into HEL compliance or wetland conservation compliance are not adversely impacted when they are seeking insurance next year and subsequent years.

Response: The interim rule changed the policy provisions to indicate that producers must have Form AD–1026 on file by June 1 prior to the sales closing date, and they must be in compliance with the conservation compliance provisions of 7 CFR part 12. For producers who have previously been required to file Form AD–1026, such producers must be in compliance with the conservation compliance provisions. For certain producers, additional time is provided to get into compliance with the conservation provisions. However, since FSA and NRCS are administering the conservation compliance programs, the provisions to provide the additional time frames to allow producers who have never before been subject to the conservation compliance provisions can be found at 7 CFR part 12 and *http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09599.pdf.*

Technical determinations regarding the conservation compliance provisions, such as whether land is highly erodible or a wetland, are made by NRCS. NRCS is also responsible for approving conservation and mitigation plans, when needed, to ensure land meets the conservation compliance requirements and conducting any compliance reviews and spot-checks. The interim rule did not address the development, approval, or enforcement of the technical requirements for conservation or mitigation plans, as these are not RMA, FCIC, or approved insurance provider responsibilities.

The details regarding the additional time afforded for certain producers to comply with the provisions, how administrative appeals affect a final determination of violation, and the differing dates for determining eligibility for FSA programs and Federal crop insurance premium subsidy due to a wetland conservation violation were not included in the interim rule. The details regarding such provisions and how they apply are contained in an amendment to the regulations at 7 CFR part 12. No change has been made.

Comment: A commenter stated section 7(h) of the CCIP Basic Provisions is poorly organized and includes repetition of Highly Erodible Land/Wetland Conservation and Form AD–1026 requirements. To streamline and eliminate any ambiguity in this section, the commenter recommended FCIC reorganize section 7(h) of the CCIP Basic Provisions as follows:

> (h) Effective for any policies with a sales closing date on or after July 1, 2015:
>
> (1) You will be ineligible for any premium subsidy paid on your behalf by FCIC for any policy issued by us if:
>
> (i) USDA determines you have committed a violation . . .; or
>
> (ii) You fail to file form AD–1026, or a successor form, with FSA by the applicable deadline to be properly identified as in compliance with the applicable conservation provisions specified in section 7(h)(1):
>
> (A) By June 1 after you make application for insurance if you demonstrate you are a beginning farmer or rancher . . . ; or
>
> (B) By June 1 prior to the sales closing date for all others.
>
> (2) To be eligible for premium subsidy paid on your behalf by FCIC, it is your responsibility to assure you meet all the requirements in section 7(h)(1) above.

Response: FCIC does not agree the suggested language streamlines, clarifies or improves the readability of the section to the extent that a change is warranted. The proposed changes may have adverse or unintended consequences. The proposed revision introduces new paragraph designations that are not necessary and create additional cross-references that can lead to greater confusion and potential for inaccurate reading. In addition, the proposed revisions could inadvertently change the meaning of the provisions. No change has been made.

Comment: A commenter requested that FCIC allow producers who are out of compliance as of June 1 preceding the sales closing date for the upcoming reinsurance year to be able to regain eligibility if they are determined to be back in compliance prior to the sales closing date for any crop on their policy.

Another commenter agreed with the requirement of maintaining Conservation Compliance in order to qualify for the insurance premium subsidy and with FCIC's approach of not denying benefits during the year in which a farm is found to be out of compliance. However, the commenter urged FCIC to reconsider the manner in which penalties are imposed in the following year. There is significant time between the start of the reinsurance year and the sales closing date for most crops, especially cotton and other spring-seeded crops. If a producer is found to be out of compliance at the beginning of the reinsurance year, the commenter encouraged FCIC to consider giving producers the opportunity to reinstate their eligibility for premium subsidies if they are able to achieve conservation compliance by the sales closing date.

Another commenter stated the proposed June 1 deadline for filing the AD–1026 form is in the regulation, but not in the statute. The commenter requested that FCIC allow producers who are out of compliance as of June 1 to be able to regain eligibility for premium subsidy if they are determined to be back in compliance before the SCD for any crop on their policy. The commenter assumed that FSA will establish procedures around the ability of producers to become eligible for premium subsidy after June 1 but prior to the SCD for any crop on their policy.

A commenter stated the proposed implementation of the new "Conservation Compliance" provisions for the Federal crop insurance program appears to be fairly straightforward with the exception of the direction FCIC has taken regarding possible penalties for producers who temporarily fall out of compliance during an insurance year. While the commenter supported maintaining producer eligibility for premium assistance during the year that a conservation compliance-related problem is recognized, the commenter believed the automatic exclusion of the producer from participating in the program the following insurance year is overly harsh and inflexible. It fails to recognize that the producer may be able to bring themselves back into compliance prior to the start of the next reinsurance year or by their next applicable sales closing date. For cotton producers in the commenter's service area, there is a nine-month difference between the start of a reinsurance year on July 1 and the applicable sales closing date for cotton of March 15. This is a significant period of time during which a producer can come back into compliance, especially if the issue that made them non-compliant was temporary or short-term in nature and can be remedied prior to the next growing season. The commenter believed FCIC should reevaluate the interim rule and revise so that it recognizes and encourages a producer to get back into compliance as quickly as possible and prior to their next applicable sales closing date in order to prevent any lapse in their ability to participate and receive premium assistance. By allowing this option FCIC will accomplish two important goals. First, it will provide a reasonable incentive to quickly address conservation compliance related issues and further the purpose of the provision to enhance environmental stewardship. Second, it will prevent the unnecessary exclusion of otherwise eligible Federal crop insurance program participants.

Response: The 2014 Farm Bill specifies, in the case of a violation, ineligibility for Federal crop insurance premium subsidy applies to the reinsurance year following the date of a final determination of a violation, including all administrative appeals. The reinsurance year runs from July 1 through June 30. This is why the June 1 date for determining compliance was used so that approved insurance providers would know before the start of the reinsurance year on July 1 who was in compliance and would be eligible for premium subsidy. However, under the commenters' proposal, it would directly conflict with the 2014 Farm Bill to allow producers to regain their eligibility during the reinsurance year when the 2014 Farm Bill expressly states they are ineligible for premium subsidy. For example, under the 2014 Farm Bill, if a producer is determined to be in violation of the conservation compliance provisions as of June 1, 2016 and all appeals have been exhausted, the producer is ineligible for Federal crop insurance premium subsidy the 2017 reinsurance year, which runs from July 1, 2016 to June 30, 2017. This means the producer would be ineligible for premium subsidy for all crops with a sales closing date within that period. Even if the producer becomes compliant in August 2016, the 2014 Farm Bill requires eligibility for the remainder of the reinsurance year. No change has been made.

Comment: A commenter stated the National Environmental Policy Act (NEPA) and Implementing Regulations NEPA requires all Federal agencies to prepare an Environmental Impact Statement (EIS) for "every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment." As a preliminary step, an agency may prepare an Environmental Assessment (EA) to determine whether the environmental impact of the proposed action is significant enough to warrant an EIS. If an EA establishes that the agency's action may have a significant effect upon the environment, the agency must prepare an EIS.

An agency does not have to prepare an EIS or EA if the action to be taken falls under a categorical exclusion (CE), which include agency-identified categories of actions that do not individually or cumulatively have a significant effect on the human environment. An EA or EIS must be prepared even for otherwise categorically excluded actions where the action may have the potential to affect the environment.

USDA regulations exempt FCIC from NEPA compliance. However, the commenter notes that actions of excluded agencies, including FCIC, are no longer categorically excluded from the preparation of an EA or EIS if "the agency head determines that an action may have a significant environmental effect."

Similarly, FSA regulations provide that "major changes in ongoing programs" or "major environmental concerns with ongoing programs" are among the categories of FSA activities "that have or are likely to have significant environment[al] impacts on the human environment." "Initial NEPA involvement in program categories" that are listed as likely to have significant environmental impacts "shall begin at the time [ ]FSA begins developing proposed legislation, begins the planning stage for implementing a new or changed program or receives notice that an ongoing program may have a significant adverse impact on the quality of the human environment."

Accordingly, CFS hereby provides notice to FCIC as the joint administrator of the crop insurance program that it must comply with NEPA because the crop insurance provisions of the 2014 Farm Bill implicate conservation programs to which NEPA applies, and may have a significant environmental effect.

The 2014 Farm Bill made two significant changes to existing agricultural programs. First, it tied the federally-funded portion of crop insurance premiums for commodities to conservation compliance. The 2014 Farm Bill requires farmers who purchase subsidized crop insurance to develop conservation plans when they grow crops on land subject to high rates of erosion. The 2014 Farm Bill reattaches soil and wetland conservation requirements to crop insurance premium subsidies, and establishes a Sodsaver provision to protect native grasslands, which prohibits recipients of crop insurance subsidies from draining or filling wetlands unless they mitigate those wetland losses. Now a producer who plows native prairie for crop production in one of the six states covered by the program will receive a 50-percentage-point crop insurance premium subsidy reduction. The prerequisite of implementing an approved conservation plan before producing a commodity on highly erodible land or converting a wetland to crop production has existed since the 1985 Farm Bill and previously affected most USDA farm program benefits, but has excluded crop insurance since 1996. The 2014 Farm Bill again links crop insurance to conservation compliance.

Second, the 2014 Farm Bill merges commodity payments into the crop insurance scheme. The 2014 Farm Bill eliminates direct commodity payments, countercyclical payments in their current form, and the Average Crop Revenue Election (ACRE) program. In place of direct payments, the 2014 Farm Bill revises the counter-cyclical payment program that was established in 2002 and the ACRE program that existed alongside direct payments into the new Price Loss Coverage (PLC) and Agriculture Risk Coverage (ARC) crop insurance options. Thus commodity support is now part of the crop insurance program.

As a result of these two significant changes, NEPA applies to the crop insurance program. First, conservation programs are subject to NEPA under FSA regulations. Because the 2014 Farm Bill explicitly links conservation compliance to the new crop insurance program, NEPA obligations attach to the new crop insurance program.

Second, the changes to the crop insurance program will significantly affect the human environment. In fact, the crop insurance-conservation program is specifically designed to significantly affect the quality of the human environment by protecting sensitive lands and preventing soil loss. Degraded soil quality has a host of serious environmental consequences, while directly undermining the ability of farmers to grow nutritious food and be resilient in the face of disruption. Soil erosion causes water pollution, impacts wildlife habitat, and threatens long-term land productivity. Soil erosion and depletion also affects air quality and climate change: Clearing land converts stored carbon into carbon monoxide, and more than a third of the excess carbon monoxide that has been added to the atmosphere has come from the destruction of soils. Releasing more carbon monoxide into the atmosphere than it can effectively absorb also causes ocean acidification and contributes to the destruction of coral reefs and other marine ecosystems.

Now, farmers who purchase or receive crop insurance will have to develop conservation plans when growing on land subject to high rates of erosion and will be prohibited from draining or filling wetlands without mitigating the losses. Approximately one third of cropland in the United States is highly erodible, meaning that these provisions affect a significant percentage of acreage. The program also limits subsidies to farmers who convert native grasslands to crop production. From 2008 to 2011, more than 23 million acres of grassland, shrub land, and wetlands were destroyed for crop production, destroying habitat that sustains many species of birds and other animals and threatening the diversity of North America's wildlife. In light of these realities, the intended result of these new provisions is to protect sensitive land and prevent soil loss. NEPA is concerned with all significant environmental impacts, not merely adverse impacts. These impacts alone are significant enough to trigger NEPA.

The new crop insurance program may also significantly, and directly, impact the environment in a negative way. The negative effects of commodity crop subsidies have been thoroughly documented. In short, subsidies—including crop insurance—encourage farmers to grow commodity crops on otherwise fallow or environmentally sensitive land. As just one example, a 2012 study by researchers at Iowa State University utilized field-level yield data up to 2006 and price data over 2005–2008, and found that up to three percent of land under the Federal crop insurance program would not have been converted from grassland if there had been no crop insurance subsidies.

With commodity crop production often comes intensive and environmentally destructive practices such as mono-cropping and heavy pesticide use. Single-crop production is more intensive and requires significantly higher usage of pesticides, herbicides, and fertilizers. Reduced crop diversity significantly increases crop losses due to insects and pathogens and reduced soil organic matter. These problems lead to increased use of pesticides and fertilizers, which in turn can increase pathogen and insect populations. Commodity-crop monoculture reduces habitat for wildlife, including birds, pollinators, and other animals that eat pest insects. In addition to reducing species richness and harming key species, this compounds the need for pesticides. On average organic farms have 30 percent higher biodiversity, including birds, pollinators, and plants, than their mono-cropped industrial counterparts. Subsidies also create higher marginal revenues for inputs (fertilizers, pesticides, herbicides, seeds, and labor), thereby motivating additional input use, by raising prices and reducing price variations in program crops. For example, compared with farmers who do not participate in commodity programs, corn farmers receiving subsidies have reported significantly increased herbicide use in all cropping sequences, "supporting the conventional view that commodity programs directly contribute to greater herbicide use in corn production." The industrial-scale use of pesticides, herbicides, and fertilizers in turn significantly affects rivers and groundwater, harming aquatic ecosystems and the life forms they support. Over half of synthetic nitrogen fertilizers used on global cereal production (including corn and soy) are lost through groundwater leaching or released as nitrous oxide into the atmosphere. Nitrous oxide is a greenhouse gas 310 times more potent than carbon monoxide, and in the United States three-quarters of it comes from agricultural soil management. The effects of commodity farming as supported by the new crop insurance program are thus serious and significant.

These impacts flow directly from the new crop insurance program—a major Federal action significantly affecting the human environment—triggering FCIC's duty to comply with NEPA in implementing the programs.

For the forgoing reasons, NEPA applies to the new crop insurance program. NEPA requires FCIC to, at a minimum, conduct an EA for the new crop insurance subsidies. FCIC's failure to comply with NEPA in implementing these programs would constitute a blatant violation of NEPA and USDA regulations.

Response: The regulations at 7 CFR part 1b provide that the FCIC is categorically excluded from the preparation of an environmental assessment or environmental impact statement unless the agency head determines that an action may have a significant environmental effect. The 2014 Farm Bill mandates the expansion of current conservation compliance requirements to apply to persons who seek eligibility for Federal crop insurance premium subsidy. However, these 2014 Farm Bill provisions do not change the existing rules regarding the technical determinations for the conservation compliance provisions, such as whether land is highly erodible or a wetland, conservation and mitigation plans, when needed, to ensure land meets the conservation compliance requirements and conducting any compliance reviews and spot-checks. Further, FCIC merely amended the policy to include the requirements of the 2014 Farm Bill, the regulations governing the conservation compliance provisions of the Food Security Act of 1985, as amended by the 2014 Farm Bill, are found at 7 CFR part 12. In addition, although Federal crop insurance participants were not previously subject to conservation compliance, the majority of insured participants were already participating in farm programs subject to conservation compliance. Therefore, the head of the agency has determined that this final rule will not have a significant environmental effect.

Comment: A commenter stated there is considerable confusion surrounding the issue of new conservation compliance rules for crop insurance.

For instance, the Background in the interim rule, in the third column of page 37157, states that "[e]ven if the insured [determined to be non-compliant on June 1, 2015, (2015 reinsurance year)] becomes compliant during the 2016 reinsurance year, the insured will not be eligible for premium subsidy until the 2017 reinsurance year starting on July 1, 2016." However, when questioned about this matter during a hearing of the House Subcommittee on General Farm Commodities and Risk Management, held July 10, 2014, Undersecretary Michael Scuse stated, "Well, remember, we're asking them to sign up that they will be in compliance on June 15th and then they are given a period of time to come into compliance." In response to a follow up question of exactly how long the producer would have to come back into compliance, Undersecretary Scuse stated that this would be established "in the rule."

The commenter agreed with the Undersecretary's point of view that the producer ought to be given time to come back into compliance. However, the interim rule, at least in the Background, appears to take a punitive approach that is inconsistent with the Undersecretary's statement. The commenter respectfully urged that the rule clarify that the producer does, in fact, have time to come back into compliance and what that time period is precisely. The commenter also urged that, beyond the rulemaking, FCIC develop a FAQ document that answers the questions concerning conservation compliance. Only the Department can provide answers that will give producers confidence in the safe harbors provided by the law and regulation.

Response: The 2014 Farm Bill states that ineligibility for Federal crop insurance premium subsidy due to a violation of the conservation compliance provisions shall apply to reinsurance years subsequent to the date of final determination of a violation, including all administrative appeals. The requirement that producers file their AD–1026 form by June 1 did not come into effect until June 1, 2015, more than a year after enactment of the 2014 Farm Bill. RMA, FSA, NRCS, agents and approved insurance providers have been conducting a significant effort to inform all producers of the conservation compliance requirement so that any producers not in compliance would have an opportunity to get into compliance prior to June 1, 2015.

Since FCIC does not administer the conservation compliance provisions or make determinations of compliance, as stated above, the details regarding the additional time afforded certain producers to comply with the provisions and how administrative appeals affect a final determination of violation are contained in an amendment to the regulations at 7 CFR part 12.

However, the Food Security Act of 1985 and the 2014 Farm Bill provide an exemption for persons who act in good faith and without intent to commit a violation. The exemption allows such persons to remain eligible for Federal crop insurance premium subsidy for a period of time if the person is taking action to remedy the violation. The determination of whether a person acted in good faith and without intent to violate the provisions is part of the administrative appeals process. Therefore, a person who meets the requirements of the good faith exemption would not have a final determination of violation unless they do not take the appropriate steps to remedy the violation within the established time period. The person would not be ineligible for Federal crop insurance premium subsidy until a final determination of violation is made. The details of the good faith exemption are contained in an amendment to the regulations at 7 CFR part 12. No change has been made in this final rule.

Comment: A commenter supported the provision in the rule for beginning farmers and ranchers concerning the deadline for filing the form AD–1026. While all other insureds must file a form AD–1026 by June 1 of any reinsurance year to be eligible for premium assistance in the next reinsurance year, beginning farmers that have not had any insurable interest in a crop or livestock operation previously, and started farming after the beginning of the new reinsurance year, have until the sales closing date to file an AD–1026. In effect, this allows a new entrant to farming the same access to premium assistance as established farmers, up until the sales closing date. While the commenter did not believe that there is any provision in the 2014 Farm Bill or in prior law that specifically authorizes this flexibility to beginning farmers and ranchers, the commenter believed that it has merit and is fair to this special group of producers.

Response: FCIC agrees with the commenter that the exception to the requirement to have form AD–1026 on file on or before June 1 prior to the sales closing date for certain producers who were not previously engaged in farming is needed and is not inconsistent with the statutory requirements. Such producers would not have known of the requirement to file an AD–1026 form by June 1 and, therefore, they cannot be penalized for non-compliance. However, the term "beginning farmer or rancher" has a specific definition that will result in the exception not being applied as intended. The intent of the exception is to provide producers who are new to or began farming for the first time after the June 1 deadline the ability to remain eligible for premium subsidy the subsequent reinsurance year. "Beginning farmer or rancher" can include producers who have been farming for a few years. Therefore, in order for the exception to be applied as intended, the reference to "beginning farmer or rancher" will be changed to reference producers who begin farming for the first time after June 1. The needed changes were provided in the Special Provisions of the applicable crop insurance policies until this final rule was published. FCIC has issued administrative procedures that describes what constitutes beginning farming for the first time, and how producers without form AD–1026 on file can self-certify that such a situation applies to them in procedures. Producers may only qualify for this exception for one year and must have form AD–1026 on file by the following June 1 to remain eligible for premium subsidy in subsequent reinsurance years. Therefore, FCIC has incorporated this change in section 6(f)(2)(i) of the CAT Endorsement, section 7(h)(2)(i) of the CCIP Basic Provisions, and section 7(i)(2)(i) of the ARPI Basic Provisions of this final rule and will remove the Special Provisions statement after this final rule is published.

Section 11007

Comment: A commenter stated the current definition of enterprise unit is "All insurable acreage of the same insured crop in the county in which you have a share on the date coverage begins for the crop year, provided the requirements of section 34 are met." With the new allowance for enterprise units by irrigation practice, the commenter does not believe this definition is sufficient. The commenter recommended FCIC revise the enterprise unit definition in the CCIP Basic Provisions as follows: "All insurable acreage of the same insured crop or crop/irrigation practice, when allowed by the actuarial documents, in the county in which you have a share on the date coverage begins for the crop year, provided the requirements of section 34 are met."

Response: FCIC agrees and has revised the definition to take into account that separate enterprise units are allowed for all irrigated acreage and non-irrigated acreage of the crop in the county.

Comment: A commenter stated when the option for enterprise unit coverage was introduced in the 2008 Farm Bill, it quickly gained popularity across the Cotton Belt. The new farm law enhances enterprise unit coverage by providing the ability to separate irrigated and non-irrigated acres when using enterprise unit coverage. However, the commenter understood that this provision will only be available when a producer has the ability to qualify for enterprise unit coverage for both their irrigated acreage and non-irrigated acreage. If a producer cannot qualify for enterprise unit coverage on both practices, that producer would then have a common enterprise unit. The commenter recommended FCIC implement the new enterprise unit provisions with greater flexibility than the commenter understood to be the case. Specifically, if a producer qualifies for enterprise unit coverage for a single practice, the producer should be allowed to select enterprise unit coverage for that practice, without impacting his ability to choose the most appropriate unit structure, be it a separate enterprise unit or optional units that meets the needs of his operation under the other practice. This would allow producers to utilize the law's intent of separating by practice and also prevent them from being penalized simply because a portion of their acreage does not meet the enterprise unit size requirements.

Another commenter stated in § 457.8, in section 34 of the CCIP Basic Provisions, the units provision, if a producer elects to insure dry land acreage planted to a specific commodity by enterprise unit, the producer is then also required under the interim rule to insure any irrigated acreage planted to that commodity by enterprise unit. The authority for separate enterprise units by practice, section 11007 of the Farm Bill, provides: "(D) Nonirrigated crops.—Beginning with the 2015 crop year, the Corporation shall make available separate enterprise units for irrigated and nonirrigated acreage of crops in counties." The purpose of the provision is to require FCIC to make separate enterprise units available to irrigated and dry land acreage planted to a commodity but to allow the producer to elect enterprise units for both or either. As a matter of policy, assuming minimum acreage requirements are met, allowing a producer to elect to insure irrigated acreage of a commodity by enterprise unit and to elect to insure dryland acreage planted to a commodity by optional or basic units or vice-versa still achieves the risk-reducing intent of enterprise units because one practice has been insured by enterprise unit rather than optional or basic units. Denying a producer the election to insure one practice by an enterprise unit and the other practice by optional or basic units may frustrate the goal of providing more options for producers by forcing the producer to insure both practices by optional or basic units. Importantly, the premium support connected with enterprise units would be unchanged by a producer's election of enterprise units for one practice and optional or basic units for the other because the premium support for enterprise units is fixed in statute and optional or basic units have already been appropriately rated.

If the purpose of section 11007 is fully effectuated, the commenter believed that the risk-reducing intent of enterprise units will be furthered, not diminished. Producers will have a more complete set of options for how best to manage risk, consistent with the goal of the Farm Bill. The commenter respectfully urged that the purpose of section 11007 of the Farm Bill be implemented accordingly.

Another commenter, regarding the proposed implementation of the "Enterprise Unit by Practice" provision, stated they believed that the proposed rule does not provide the degree of flexibility the commenter expected in this provision. The commenter strongly supported the provision based on their understanding that producers would be able to select the enterprise unit structure for a single practice (*i.e.*—non-irrigated), as long as acreage insured under that practice meets the minimum requirements to be a stand-alone enterprise unit, without compromising their ability to select a different or more suitable unit structure for a different practice (*i.e.*—irrigated). This flexibility provides the insured the ability to match the most appropriate insurance unit structure to the predominant risk associated with a given practice. The commenter believed the current interpretation of the provision by FCIC does not fully recognize the intent of Congress to provide meaningful flexibility to program participants. Given that the overarching goal of this provision is flexibility, the commenter believed any concern or intent from Congress to implement the provision in a more restrictive manner as FCIC has proposed would have been specifically indicated in the legislative language. The commenter urged FCIC to reconsider their current interpretation in light of this commentary and revise this provision accordingly.

Response: The text of Section 11007 states that "the Corporation shall make available separate enterprise units for irrigated and nonirrigated acreage of crops in counties." Under the plain meaning of the text, this means two separate enterprise units. Therefore, FCIC has made changes to allow separate enterprise units (not policies) by practice, *i.e.* one enterprise unit for irrigated acreage and one enterprise unit for non-irrigated acreage. Since the provision provides for two enterprise units and does not change or otherwise modify the definition of an enterprise unit, FCIC interpreted this to mean that the existing regulation for an enterprise unit remained overarching and that all acreage of the crop in the county had to be insured as an enterprise unit regardless of construct as a single enterprise unit or two separate enterprise units, one for all the irrigated acreage in the county and one for all the non-irrigated acreage in the county. To allow producers to choose smaller unit structures on some acreage of the crop in the county, such as optional and basic units, for one of the practices is counter to this intent. In addition, allowing an enterprise unit for one practice and another unit structure for the other practice complicates program administration and premium subsidy determination. Enterprise unit subsidies are based on the average enterprise unit discount received by growers. The enterprise unit discounts themselves are affected by the size of the unit—the larger the acreage in an enterprise unit, the greater the discount (and vice-versa). As growers are given additional flexibility to reduce the size (less acres) of their enterprise unit, then the enterprise unit discount becomes smaller. This brings into question whether the premium subsidy rates offered for enterprise units would need to be revised downward accordingly. To the extent that the average size of enterprise units moves closer towards the average size of optional units, the premium subsidy rates for enterprise units must also move closer towards the premium subsidy rates for optional units. No change has been made.

Comment: A commenter stated the interim rule stipulates timelines for implementing separate enterprise units and coverage levels for irrigated and dryland acreage. These provisions will greatly benefit growers in areas that utilize irrigated agriculture. Producers who use both practices in their operations are currently unable to fully realize the benefits of using enterprise units due to the wide variation in production between their irrigated and non-irrigated crops. As producers in Texas have faced multiple years of extreme drought, their dryland yields have plummeted, bringing enterprise unit yields down significantly even though the irrigated acreage was not as severely affected. The result is reduced coverage and crop insurance policies that do not reflect average production. The ability to have separate, distinct levels of coverage on irrigated and non-irrigated acres will allow farmers to create a better risk management plan for their operation. The commenter urged FCIC to implement this provision as soon as possible. By delaying the implementation of these provisions until spring of 2015, FCIC has put winter wheat producers at a distinct disadvantage to growers of other crops.

Response: The changes mandated by the 2014 Farm Bill impact almost all county crop programs within the Federal crop insurance program. Unfortunately, given the magnitude of the work required, FCIC was unable to implement the provision for crops with a contract change date prior to November 30, 2014. The actuarial documents specified the ability to make this election beginning with 2015 crop year spring crops with a contract change date of November 30, 2014, and later.

Comment: A commenter stated they identified a major flaw in section 34(a)(4)(viii)(C)(*1*) of the CCIP Basic Provisions as currently proposed. This section needs to be clarified to indicate that if the insured does not qualify for enterprise units by practice that he or she then has to automatically default to enterprise unit, provided that he or she qualifies for such unit structure on a crop basis. If it is subsequently determined that the insured does not qualify for enterprise unit either, the unit structure would then revert to basic units or optional units, whichever the insured reports on the acreage report and qualifies for. There should not be an option for the insured to not elect to have enterprise unit simply because he or she does not qualify for enterprise units by practice up to the acreage reporting date. The rationale for this is that the insured has to make the decision to elect enterprise units or enterprise units by practice by the sales closing date. Therefore, if the insureds do not qualify for enterprise units by practice the commenter felt it should not allow insureds the opportunity to not have enterprise units up to the acreage reporting date. There are valid reasons for requiring the enterprise units or enterprise units by practice election by the sales closing date and if this provision is not revised it would allow insureds the opportunity to elect enterprise units by practice by the sales closing date, even if they know that they will not qualify for such election, and then have the option to decide by the acreage reporting date if they want to go with enterprise units or change to basic or optional units, whichever they qualify for. The current language as structured allows insureds the opportunity to circumvent the sales closing date deadline for this election which is counter to the requirement that this election be made by the sales closing date. It creates an unintended loophole that producers could use to circumvent the sales closing date deadline for this election. If this provision is not changed it subjects the Approved Insurance Providers to possible adverse selection by producers since they would now be allowed to decide if they want to have enterprise units up to the acreage reporting date. In summary, the commenter stated the proper way to administer this provisions is to automatically apply enterprise units if the insured does not qualify for enterprise units by practice and then revert to basic or optional units if the insured does not qualify for enterprise units either (similar to how the commenter would handle this if it was discovered after the acreage reporting date except that optional units would also be an option in addition to basic units).

Response: FCIC disagrees with the commenter. There is nothing in the policy that requires the election of unit structure by the sales closing date. Such decisions have always been made by the acreage report once the producer knows what crops/types/practices have been used. It is impossible to make such determinations by the sales closing date. However, to protect program integrity, coverage levels must be selected by the sales closing date because there is always a potential for loss before the acreage reporting date and it would adversely affect program integrity to allow producers to change their coverage level after a loss has occurred. Even though the producer may request separate coverage levels if authorized by type or practice, it cannot be binding on the producer because the producer may elect not to plant to one of the selected types or practices. This will not be known until the crop is planted, which may be months after the sales closing date. Allowing the insured to choose, before the acreage reporting date, one enterprise unit, or basic or optional units depending on which the insured has reported on the acreage report, allows flexibility for those insureds who would not have elected one enterprise unit but for the new enterprise unit by practice election. Removing this flexibility may deter insureds from electing separate enterprise units by practice. FCIC does not allow this flexibility after the acreage reporting date. If after the acreage reporting date, an insured who elected separate coverage levels by practice does not qualify is automatically applied basic or optional units, depending on which they have reported on their acreage report. No change has been made.

Section 11009

Comment: A commenter stated their reading of the regulation indicates that USDA is limiting the use of actual production history (APH) based on production data availability. The commenter strongly recommended that APH Yield Adjustment Option be implemented for all producers without delay. This is an important provision especially for very progressive farms that have excellent production results.

Another commenter stated erosion of APH due to consecutive years of disaster is an issue the wheat industry has been fighting for many years. With wheat being grown in some of the most diverse regions of the country, wheat farmers can be devastated with drought, floods or freezes in any given year. This provision would be very beneficial to wheat growers across the country, primarily in areas where they are dealing with multi-year disasters. FCIC announced that this provision will not be available for the 2015 crop year which has left a number of wheat farmers frustrated. The commenter would appreciate FCIC doing everything in its power to make this provision available to our growers for 2015. The commenter is specifically concerned over continued economic injury to those who can least afford it after years of financial stress due to ongoing drought. The commenter believed this provision will go a long way toward their goal of ensuring a producer is paying for coverage that matches his or her production expectation.

Another commenter stated this provision will provide immediate relief to farmers who have suffered from multiple years of extreme weather disasters. The provision is not likely to trigger frequently, but will aid farmers in disaster areas to secure crop insurance coverage that meets average production estimates. A delay in implementation for the APH provision will result in one more year of eroding APH levels for growers across the Southern Plains region who are currently experiencing a record breaking, multiple year drought. The APH provision should be implemented immediately to adequately protect farmers and maintain the strength of the crop insurance program. As several key farm policy leaders have mentioned, if the provision cannot be implemented in 2015 for all areas and all crops, the commenter urged FCIC to target those areas most likely to benefit from the provision.

Another commenter stated they appreciated FCIC's work in making other provisions included in the 2014 Farm Bill applicable for the 2015 insurance year including: The ability to insure at different coverage levels by practice; enterprise unit coverage by practice; and the beginning farmer provisions. One provision that FCIC has indicated will not be available in 2015 is the APH adjustment. This provision is especially important for portions of the Cotton Belt who have recently incurred several years of historic drought conditions. Again, with insurance being the foundation of risk management for cotton producers, the commenter urged FCIC to continue to review every avenue possible for implementation of this important provision.

Another commenter stated concerning the implementation of section 11009 of the 2014 Farm Bill allowing insureds to exclude certain yields, the commenter understood there has been considerable discussion regarding the feasibility of an implementation in time for the 2015 reinsurance year. The commenter also supported the provision and its timely implementation and the commenter offered their expertise and their agent members in assisting to achieve this objective that is so important to producers struck by natural disasters, particularly the drought-stricken producers of recent years.

A commenter stated "Section 11009—The "APH Adjustment" provision is one that is of particular importance to the commenter's membership and is among their top priorities for implementation. Based on previous statements from FCIC, the commenter continues to be concerned that this provision will not be implemented in time for the 2015 insurance year. The commenter appreciated FCIC's willingness to continue to evaluate possible avenues for partial implementation of the provision for those regions of the country that are most impacted by the current drought and for which this provision was intended to provide relief. The commenter believed that FCIC is making progress in this regard as it has become clear in recent weeks that FCIC has performed a significant amount of data collection and analysis in high impact regions. Based on these observations the commenter believes that FCIC can realistically implement this provision at a significant level for 2015. The commenter encouraged FCIC to continue to work on this issue and to make every effort to make this provision available to cotton and grain producers in the regions that are most in need, specifically Texas and Oklahoma.

Response: FCIC had a number of 2014 Farm Bill provisions that mandate a 2015 crop year implementation. In accordance with these mandates by Congress, FCIC had to devote considerable resources to this effort. Further, while many of the crop insurance provisions in the 2014 Farm Bill were found in previous versions, section 11009 was not included until the final enactment of the 2014 Farm Bill. Due to many 2014 Farm Bill programs being completed ahead of schedule, and the timing of these completions, FCIC was able to implement this provision for select spring crops for the 2015 crop year but given the sheer amount of work required to implement this provision for all crops, in all counties, by irrigated and non-irrigated practice, FCIC simply did not have the time or the resources to implement the provision for all crops and counties.

Comment: A commenter stated section 11009 of the 2014 Farm Bill allows producers to exclude historic yields when county yields were at least 50 percent below the ten-year simple average. Agricultural producers already receive generous premium subsidies in addition to favorable provisions allowing any producer to receive crop insurance subsidies regardless of the risk profile of the farmland. Basing these taxpayer-subsidized guarantees on an "actual" production history that cherry-picks the best years of production is fiscally reckless. APH should reflect the history of production actually experienced, rather than some aspirational potential harvest that would have occurred if not for the growing conditions actually experienced. The commenter suggested this provision not be implemented. If it is, the commenter suggested a surcharge be charged for every yield plug inserted in a producer's APH, to account for the likelihood of yields falling short of these artificially high guarantees.

Response: Since the provisions regarding exclusion of yields were mandated by the 2014 Farm Bill, FCIC is required by law to implement the changes. FCIC must also, by law, set premium rates sufficient to cover anticipated losses plus a reasonable reserve. FCIC has revised the premium rate calculations to account for the increase in a grower's coverage, and potential losses, due to the exclusion of certain yields from a producer's actual production history.

Comment: A commenter stated the new CCIP Basic Provisions section 5 states ". . . the per planted acre yield was at least 50 percent below the simple average of the per acre planted yield for the crop in the county for the previous 10 consecutive crop years." The commenter does not believe FCIC intended to use different phrasing for per planted acre yield. The commenter recommended FCIC revise this section to only use the phrase "per planted acre yield" to accurately reflect that the yields to be considered are on a per-acre basis, but are limited to planted acreage.

Response: FCIC agrees with the commenter and has revised the provisions accordingly.

Section 11014

Comment: A commenter stated section 11014 of the 2014 Farm Bill reduces crop insurance premium subsidies on native sod acres in certain Midwestern states. This provision only applies to plots of land that are larger than five acres. Due to the unintended consequences and large public costs of tearing up native sod for cropland production, this threshold should be reduced to zero acres, or at a minimum, ensure that producers tear up no more than five acres across all of their farms, regardless of location, joint ownership, etc. The commenter believed taxpayers should not subsidize the conversion of sensitive cropland to crop production. Proper enforcement and monitoring of this provision should also be prioritized to ensure that taxpayer subsidies are not subsidizing risky planting decisions.

Response: The 2014 Farm Bill specifically states "The Secretary shall exempt areas of 5 acres or less". Therefore, the 2014 Farm Bill does not provide the authority to change this threshold. FCIC has made changes to exempt a total of five acres or less per county, per producer, across all applicable insured crop policies cumulating each year until the 5-acre threshold is reached. Once a producer converts more than five acres of native sod, the reduction in benefits will apply to all native sod acreage going forward. The premium subsidy reduction of 50 percentage points is required by the 2014 Farm Bill on converted native sod. This guarantees that taxpayers will not bear the risk of the conversion of native sod acreage. No change has been made.

Comment: Several commenters stated under the interim rule, a producer could convert native sod to an annual crop not covered by their chosen crop insurance policy and choose not to insure it during the first four crop years. During the fifth crop year the producer could add the converted acres to their policy and receive full Federal crop insurance benefits. For example, a crop insurance policy in the six sodsaver states would be for corn, soybeans, and wheat. A producer could plant annual crops of sunflowers, sorghum, millet, or oats during the first four years native sod is cropped and not include them in their crop insurance policy. The fifth year they could plant corn, soybeans or wheat and receive full crop insurance benefits. A producer could alternatively plant a perennial crop, like alfalfa, during the first four years of cropping native sod, receive full premium subsidies for forage insurance, and then again in year five plant an insurable annual crop and never be subject to sodsaver disincentives.

The commenters recommended to avoid these potential loopholes, minimize taxpayer liabilities, and maintain Congressional intent, any native sod acreage converted after February 7, 2014, should be subject to sodsaver premium reductions for the first four years of Federally insured crop production. For example, a producer who converted 160 acres of native sod in March 2014 plants alfalfa on that acreage in 2014–2017, and plants Federally insured wheat in 2018 should be subject to four years of sodsaver disincentives beginning in year 2018. This would ensure that the disincentive to convert native sod to cropland is fulfilled as intended by Congress.

Response: The 2014 Farm Bill states the reduction of benefits are during the first four crop years of planting on native sod acreage. These reduction of benefits only apply to annual crops planted during the first four crop years of planting on such acreage. FCIC does not have the authority to change these requirements and make them more restrictive. Therefore, no change has been made.

Comment: Several commenters stated the sodsaver provisions define native sod as any land that has no substantiated cropping history prior to February 7, 2014. The statute reduces Federal crop insurance premium benefits by 50 percentage points following conversion of native sod, limits transitional yields to 65 percent, and prohibits yield substitution during the first four years an annual crop is

Federally-insured. Substantiation of cropping history should include a combination of verifiable FSA records and/or spatially-explicit data tied to those tracts. The commenters stated simply providing seed or input cost receipts with no verifiable tract-level spatial information or supporting FSA documentation should not suffice as adequate substantiation of cropping history.

A few commenters stated a fact sheet published in June titled "Native Sod Guidelines for Federal Crop Insurance" does not provide any limitation on the types of evidence that may be used to prove that land has been tilled. Instead, the guidance provides seven examples of acceptable documentation. Moreover, the interim rule stated that the absence of tillage will be "determined in accordance with information collected and maintained by an agency of the USDA or other verifiable records that you provide and are acceptable to us[. . .]" The commenters were concerned that this flexibility will result in the use of unreliable evidence of tillage. Therefore, the commenters recommended that if a producer cannot provide FSA, NRCS, or Common Land Unit documentation that demonstrates a cropping history on the land, there must be a body of spatially explicit evidence (*e.g.*, GIS planting/harvest maps vs. simply seed or other input receipts with no verifiable spatial information) showing the cropping history clearly. The commenters strongly opposed the use of receipts and/or invoices as evidence of tillage, and the commenters urged that the rule explicitly exclude this as a form of documentation. The commenters believed third-party verification will help ensure accurate "substantiation" of prior cropping history. A commenter further recommended that the final rule explicitly exclude the use of receipts and/or invoices as documentation of tillage.

Response: FCIC agrees that the evidence for a cropping history must be tied to the specific acreage. Therefore, FCIC has removed from its issued procedures the reference to "receipts and invoices" as a form of documentation that may be used to substantiate the ground has been previously tilled for the production of a crop. In addition, FCIC has revised and issued procedures requiring the use of USDA documentation when available, including FSA and NRCS documentation.

Comment: Several commenters stated under the interim rule, crop insurance agents would determine the classification of native sod. Three significant factors make this process unworkable: Inadequate training on landscape classification, lack of access to FSA information, and conflict of interest. Crop insurance agents are trained in crop insurance regulations, coverage, and processing. Their responsibilities require considerable knowledge of a number of processes. Adding another component starkly foreign to their existing heavy workload and for one which few crop insurance agents are trained is not an effective method for processing native sod determinations. This would likely result in a significant rate of errors, leading to the need for new determinations by a trained staff of experts.

The commenters also stated that functionally, crop insurance agents have access to their own records regarding the cropping history of insured fields. However, that data often does not include the full cropping history of a field. Many fields may have data and history not accessible in insurance files. Often only FSA files have information on cropping history. This would require all crop insurance agents to contact FSA offices to obtain all information. It would simply be easier for FSA to make the determination and to remove the extra step of having the crop insurance agent make the inquiry into FSA.

For many crop insurance agents, selling crop insurance is their livelihood. Placing them in charge of making native sod determinations, what is and is not insurable, stands in a stark conflict of interest. In the free market of crop insurance, if a farmer is not happy with the decision of an agent, they can simply go to another agent. This threat of lost business for upholding the sodsaver provisions could punish crop insurance agents who do the right thing. It is unfair to place that burden on crop insurance agents. Here again, it is better to leave native sod determinations to an independent third party and in particular, to the FSA since they already possess much of the necessary data.

A few commenters stated the FSA and RMA have the ability, expertise and resources to work together to provide independent third-party verifications in a timely and accurate manner.

Response: Native sod guidelines apply to all counties in Iowa, Minnesota, Montana, Nebraska, North Dakota, and South Dakota. An insured's benefits are reduced if they till native sod acreage to grow an annual crop during the first 4 crop years they are covered by Federal crop insurance for that acreage. Native sod acreage is acreage that has never been tilled or that the insured cannot prove to have been previously tilled for crop production. To prove that acreage was previously tilled, the insured must provide documentation to the approved insurance provider. Acceptable documentation may include, but is not limited to:

(1) A Farm Service Agency (FSA)–578 document showing the crop that was previously planted on the requested acreage;

(2) A prior crop year's FSA–578 document showing that the requested acreage is classified as cropland;

(3) A prior crop year's Common Land Unit (CLU) Schema (RMA provides this to approved insurance providers), presented in a map format that contains the farm number, tract number, field number, CLU classification (the cropland classification code is '2'), and calculated acres by field;

(4) Receipts and/or invoices from custom planters or harvesters identifying the fields that were planted or harvested;

(5) A Natural Resources Conservation Service (NRCS) Form CPA–026e identifying the acreage with a "No" in the Sodbust column and a "Yes" in the HEL column;

(6) An NRCS Form CPA–026e identifying the acreage with a "Yes" in the Sodbust column and a determination date on or before February 7, 2014; or

(7) Precision agriculture planting records and/or raw data for previous crop years, provided such records meet the precision farming acreage reporting requirements.

Therefore, agents do not determine the classification of land as native sod but rather the acreage itself and records provided by the producer to the approved insurance providers will be the basis for such determinations. The agent's role in native sod classification is to gather the documents provided by the insured to submit to the approved insurance providers or FCIC. Since agents do not make the determination, approved insurance providers or FCIC acts as a third-party verifier. No change has been made.

Comment: A commenter was not in favor of the provisions regarding native sod. The commenter recommended the determination of whether a parcel of land is prairie, or that it once was cultivated, should be made by the USDA as opposed to crop insurance agents.

Response: Since the provisions regarding native sod contained in this rule were mandated by the 2014 Farm Bill, FCIC is required by law to implement the changes. As stated above, determinations are made based on records provided by the producer to approved insurance providers. Agents do not make the determination. No change has been made.

Comment: Several commenters stated FSA and RMA should monitor and provide publically available new breakings reports each year. This requirement was highlighted in the 2014 Farm Bill, which directs USDA to report changes in cropland acreage at the county level (including changes from non-cropland to cropland) since 2000 and on an annual basis post-enactment of the 2014 Farm Bill. The reporting requirement within Sec. 11014 Crop Production on Native Sod (Subsection C "Cropland Report") also directs USDA to report changes in cropland acreage. While not explicitly stated, the intent of this subsection was to monitor and report changes in native sod acreage. Simply reporting annual cropland acreage does not achieve this goal and would be duplicative of other ongoing USDA cropland reporting efforts. According to USDA Bulletin—MGR–11–006, FSA should already be tracking and reporting new breakings each year.

The commenters recommended FSA and RMA work together to monitor and provide annual new breakings reports at the county-level to measure the effectiveness of these policies, maintain public transparency, and help inform future policy making decisions. This can be done in a timely and accurate manner without jeopardizing landowner confidentiality. Specifically, the commenters asked USDA to develop and maintain a county-level "data field" of new breakings with no prior cropping history as they update their IT technology infrastructure. A commenter recommended that in order to track the impact of policies on grassland loss and the resulting impacts on wildlife, FSA must produce an annual report that tracks the conversion of native grasslands into row crop production. Another commenter stated information about new land breakings should be made available to the public on an annual basis.

Response: The 2014 Farm Bill provides that a cropland report shall be required to be provided to the specific congressional committees indicating the changes in cropland acreage by county and state from year to year. Congress provided no other interpretation or intent other than what is provided in the 2014 Farm Bill. Therefore the report will be constructed according to the 2014 Farm Bill language. FSA is the lead agency in preparing the cropland acreage report because they have a more complete data set of the changes in cropland acreage. FCIC works with FSA, providing any data applicable and appropriate, to provide this report to specific congressional committees.

Comment: Several commenters stated the sodsaver provisions include a *de minimis* exemption for lands five acres or less. That means producers can convert up to five acres of their land without being subject to sodsaver provisions. The interim rule is unclear whether this five-acre exemption is annual or cumulative over time. The intent of this *de minimis* provision was not to encourage conversion of five acres of native sod for a particular tract in year one, five more acres in year two, five more acres in year three, etc. Instead, it was intended to minimize conversion of native sod, like in the case of field round-outs, and avoid slowly converting native tracts over time.

The commenters recommended a cumulative five-acre limit apply to all land that the producer is a property owner, operator, or tenant, similar to current FSA policy for conservation compliance provisions.

Response: FCIC agrees that the interim rule was ambiguous. FCIC also agrees that the actual text and intent of the provision in the 2014 Farm Bill is to discourage conversion of native sod and to make this determination on an annual county and crop basis would allow the continued slow conversion over time. Therefore, FCIC has determined native sod acreage will be determined on a cumulative basis over time by county. FCIC procedures will be revised to require producers to report native sod acreage by insured crop of five acres or less beginning with the 2017 crop year. Once a producer breaks out more than five acres cumulatively across all insured crops dating back to the 2015 crop year, the provisions for reduced benefits due to converting native sod will be applied to the current crop year's insured native sod acreage and to any native sod acreage broken out in all subsequent crop years.

Comment: A commenter supported the provision that indicates the *de minimis* acreage for the native sod provision to apply is five acres. This was in the earlier statutory provisions where the new sodsaver provisions were inserted, so the five acre minimum continues to apply.

Response: FCIC agrees with the commenter and has retained the five-acre *de minimis* provision in the final rule but has also made revisions so that the five-acre rule applies on a cumulative basis over time by county.

Comment: A commenter stated they are glad that the rule appears to have incorporated the legislative provisions for sodsaver very effectively. The rule includes a new definition of "native sod" that references: (1) Absence of tillage; and (2) vegetative plant cover of native grasses, forbs, or shrubs as well as the trigger date of February 7, 2014, concerning potential violation. It also includes the specific listing of states covered by this aspect of the rule and removes the prior provision of the "Prairie Pothole National Priority Area" and the option formerly available for governors in those states. In the rule, if the native sod acreage is located in any of the listed states of Iowa, Minnesota, North Dakota, South Dakota, Nebraska, and Montana and tilled and planted, after February 7, 2014, to an annual crop during the first four crop years the rule reduces the insurance liability to be 65 percent of the protection factor and reduces the premium subsidy by 50 percentage points. The rule indicates that if the premium subsidy applicable to these acres is less than 50 percent before the reduction, then no premium subsidy at all would be available. However, the commenter did not find anything in the rule that bars yield substitution as specified in the native sod statutory provisions. While the commenter supported what is provided for native sod in the interim rule, they urged FCIC to include in the final rule the bar on yield substitution for violations and consider an amendment to the interim rule to include this important statutory provision.

Response: FCIC agrees with the commenter that the 2014 Farm Bill required yield substitution be disallowed on native sod acreage. However, by restricting the native sod acreage yield guarantee to 65 percent of the insured's applicable transitional yield, yield substitution cannot be utilized on native sod acreage because yield substitution is only applicable when the actual yields in the insured's production history database are less than 60 percent of the applicable transitional yield. Therefore, yield substitution would not be applicable to native sod acreage. To avoid any confusion, FCIC did not include this restriction to yield substitution in the interim rule and it is not necessary in the final rule. No change has been made.

Comment: A commenter stated the language in item e. of the background and in section 9(f) of the CCIP Basic Provisions indicates that section 9(e) is not applicable to acres of native sod acreage that is five acres or less in the county. The commenter stated they received additional clarification from FCIC based on the procedures issued for native sod as a part of Information Memorandum: PM–14–027 that the five acres applies on a crop and county basis. For example, if an insured tilled and planted four acres of native sod to corn and tilled and planted a different tract of four acres of native sod in the same county and year to soybeans that this would be allowable and that such acreage would not be subject to the reduction of benefits for the first four years. The language in this section of the provisions should be revised to be consistent with the procedural interpretations that are being made by the FCIC that the five-acre threshold for native sod is based on the crop and county.

Response: As stated above, FCIC has determined that to allow determinations of the five-acre threshold by crop and county was inconsistent with the 2014 Farm Bill. Instead, native sod acreage will be cumulative over time by county to prevent the scenario stated above where producers continue to slowly convert new land by simply planting the acreage to a different crop on the acreage. Once a producer breaks out more than five acres cumulatively across all insured crops dating back to the 2015 crop year, the provisions for reduced benefits due to converting native sod will be applied to the current crop year's insured native sod acreage and to any native sod acreage broken out in all subsequent crop years. Since the native sod acreage is cumulative for all insured crops by county, a specification by crop is no longer needed.

Comment: A commenter stated since the rule was not issued until July 1, 2014, producers who made investments to prepare ground for planting in 2014 had no way of knowing their decisions would result in a reduction of premium subsidies and production guarantees. Applying these penalties after-the-fact is unreasonable. The commenter proposed the rule be modified to prevent this unintended consequence by striking "and is planted to an annual crop" from section 9(e) of the CCIP.

The suggested change will also ensure that it conforms to the agency's definition of native sod (which makes no reference to a restriction on acreage being planted for crop year 2014).

Response: FCIC agrees and has revised the provisions of the CCIP Basic Provisions and the ARPI Basic Provisions accordingly.

Section 11015

Comment: A commenter stated section 11015 of the 2014 Farm Bill allows producers to receive taxpayer subsidies for separate coverage of irrigated versus non-irrigated cropland in a county. Agricultural producers have access to a suite of unsubsidized risk management options; some of the primary risk management techniques are diversification of crops, use of hybrids, and irrigation practices. Taxpayers should not subsidize risk management options that are readily available and already widely used in the private sector. At a minimum, when implementing this provision, the commenter recommended FCIC reduce the likelihood that producers shift acreage between irrigated and non-irrigated acres after this rule is finalized, a likely unintended consequence if adequate measures are not taken in advance.

Response: When enacting this provision, Congress observed that the risks relative to producing crops on dry land acreage versus irrigated acreage are considerably different, and that many insureds seek different coverage levels that are tailored to those varying risks. An insured must make an election for separate coverage levels for irrigated and non-irrigated acreage by the sales closing date and must meet all the policy requirements to insure their acreage under an irrigated practice. If the insured does not meet the policy requirements for insuring a crop under an irrigated practice by the acreage reporting date, the coverage level percentage they elected for the non-irrigated practice will be used to insure all acres qualifying for a non-irrigated practice. Therefore, FCIC does not believe there is a risk that insureds will shift acreage between irrigated and non-irrigated acreage. Insureds can only insure acreage as irrigated for which they have an adequate amount of water to irrigate as specified by good farming practices for the area. Further, they have to actually apply the irrigation water to the acreage in the recommended amounts and intervals or any subsequent loss will be considered due to poor farming practices and no indemnity may be due. No change has been made.

Comment: A commenter supported a producer's ability to purchase separate insurance for irrigated versus dry-land production. This Farm Bill provision was supported by the U.S. cotton industry and will be extremely beneficial to cotton producers. The commenter commended FCIC for making this change available for the 2015 crop year.

Response: All acreage of the crop in the county must be insured under a single policy, but producers will now have the option of selecting different coverage levels for the irrigated and non-irrigated practices.

Section 11016

Comment: A commenter strongly recommended that USDA expand incentives for beginning and young farmers and ranchers to Military Veterans and urged an increased premium subsidy for this segment of farmers.

Response: FCIC has implemented the beginning farmer and rancher provisions in a way that is fair to all military personnel and consistent with the Joint Explanatory Statement of the Committee of Conference, which states the Managers intend this section to be implemented in a manner that does not discriminate against producers who grew up on a farm or ranch, left for post-secondary education or military service, and returned to the farm or ranch. When calculating the five crop years in this section, the Managers intend that any year when a producer was under the age of 18, in post-secondary studies, or serving in the U.S. military should not be counted. The implementation of this provision has been done to give the maximum benefit possible to military veterans as allowed by law. No change has been made.

Comment: A commenter stated as the average age of farmers increase, it is imperative for U.S. agriculture to encourage more new and beginning farmers. The commenter believed the 10 percentage point premium subsidy increase for beginning farmers is an important provision that can allow a new producer to possibly purchase higher levels of coverage or provide a savings in insurance premiums that can be used for further investments. For many of these individuals, the prospect of starting an operation from the bottom up is nearly impossible due to the capital costs and credit availability. A more common practice is for new and beginning farmers to form partnerships within established operations with the intention of taking over the operation as the more established producer retires. FCIC's exclusion of these individuals by limiting the increased premium subsidy to only operations in which all of the substantial beneficial interested holders qualify as a beginning famer severely limits the reach of this provision. The commenter understood that the percentage of substantial beneficial interest holders is noted within the insurance documents. The commenter recommended that FCIC prorate the 10 percentage point increase in relation to the new and beginning farmer's percentage of substantial beneficial interest. This would allow more beginning farmers to utilize this provision and not put disadvantages on the type of partnerships that represent the only option for some beginning farmers to enter farming.

Response: Implementing the provision as suggested by the commenter would extend beginning farmer and rancher benefits to individuals who have previous farming experience and who are not the intended target of the 2014 Farm Bill. The 2014 Farm Bill defines a beginning farmer or rancher as one who has not actively operated and managed a farm or ranch with a bona fide interest in a crop or livestock as an owner-operator, landlord, tenant, or sharecropper for more than five crop years. Since the 2014 Farm Bill specifically limits benefits to producers with five crop years or less of insurable interest in any crop or livestock, no change has been made.

Comment: A commenter stated the language in item g. of the background describes the additional crop insurance incentives for beginning farmers and ranchers. This includes allowing the producer who qualifies as a beginning farmer or rancher to use the yield history from any previous involvement in a farm or ranch operation. The commenter questioned if a producer qualifies to use four years of history from another operator, can he/she pick and choose which year(s) to use or must all four years be used if he/she chooses to use such records. In addition, this item indicates that years of insurable interest can be excluded if earned while under the age of 18. The commenter questioned if it mattered when the person in question turns 18. For example, if the beginning farmer or rancher applicant turns 18 on December 31, after the crop year has already ended, the commenter questioned if he/she is able to exclude that crop year for beginning farmer or rancher purposes. The commenter questioned if the fact that he or she turned 18 during the same calendar year would disallow that year from being excluded for beginning farmer or rancher purposes.

Response: FCIC issued procedures allow a beginning farmer or rancher to use the APH of the previous producer when the beginning farmer or rancher was previously involved in the farming or ranching operation. The insured may choose how many years in which to transfer but the history being transferred must start with the most recent crop year and there must not be a break in continuity in the crop years being transferred. Therefore, there are limitations on the insured's ability to pick and choose which years to transfer. FCIC issued procedures specify that an individual may exclude a crop year as insurable interest if the insurable interest in the crop occurred while the individual was under the age of 18, which includes any crop year in which a beginning farmer or rancher turns 18.

Comment: A commenter stated FCIC needs to clarify that a non-individual insured person may qualify as a beginning farmer or rancher when all the individual substantial beneficial interest holders qualify as beginning farmers or ranchers. The commenter recommended FCIC revise the last sentence in the definition of "beginning farmer or rancher" as follows: ". . . may be eligible for beginning farmer or rancher benefits if there is at least one individual substantial beneficial interest holder and all individual substantial beneficial interest holders qualify as a beginning farmer or rancher."

Response: FCIC agrees with commenter and has revised the definition of "beginning farmer or rancher" accordingly.

Comment: A commenter stated section 3(l)(1) of the CCIP Basic Provisions indicates that the person who qualifies as a beginning farmer or rancher can use the APH of the previous producer of the crop or livestock on the acreage he or she was previously involved with. This section of the policy should be clarified to indicate the person who qualifies as a beginning farmer or rancher can only use the year(s) he or she was a part of the decision-making or physical involvement which may not be all years of past history from the previous producer. The way this section is currently written it could be construed that all years from this other producer can be used which may not always be the case if the beginning farmer or rancher was only involved with some of those years of APH.

Response: Unlike existing transfer of APH data requirements contained in FCIC-issued procedures, the number of years of production history that may be transferred is not limited by the number of years the beginning farmer or rancher was previously involved in the other person's farming or ranching operation. However, a beginning farmer or rancher can only use another person's production history for a crop that the beginning farmer or rancher was previously involved in. Since the 2014 Farm Bill used the phrase "actual production history of the previous producer," FCIC interprets that to include all of the years of actual production history of the previous producer on the acreage, not limited to just those years the beginning farmer or rancher was involved in the operation. If the beginning farmer or rancher was involved with the livestock, they can use the other person's livestock records. If the beginning farmer or rancher was involved with a crop, they can use the other person's crop production records. Only the production history of the specific acreage being transferred may be used by the beginning farmer or rancher. No change has been made.

Comment: A commenter recommended section 36 of the CCIP Basic Provisions should be revised to indicate that if it is later determined that the producer does not qualify as a beginning farmer or rancher, or once the producer has produced a crop for more than five years and no longer qualifies as a beginning farmer or rancher, that the excluded actual yield(s) will then change from 80 percent of the applicable transitional yield to 60 percent of the applicable transitional yield. The commenter stated this language needs to clarify that the 80 percent of the applicable transitional yield is not retained once the producer no longer qualifies as a beginning farmer or rancher.

Response: Provisions and benefits regarding beginning farmer or rancher are only applicable when a producer qualifies as a beginning farmer or rancher. Although the policy is continuous, the insured must meet the terms and conditions of the policy each crop year and must qualify for beginning farmer or rancher benefits each crop year. That means that in those years the producer qualifies as a beginning farmer and rancher, the producer will receive 80 percent of the transitional yield. However, after five years, the producer's own yields are used to establish the APH and transitional yields are no longer used. No change has been made.

Comment: A commenter recommended FCIC add a comma in section 36(c) of the CCIP Basic Provisions as follows: ". . . qualify as a beginning farmer or rancher, in which case. . ."

Response: FCIC agrees with commenter and has revised the provisions accordingly.

Section 11019

Comment: A few commenters stated the term "reinstatement" used in section 2(k)(2)(iii)(B)(*3*)(*i*) of the ARPI Basic Provisions and section 2(f)(2)(ii)(B)(*3*)(*i*) of the CCIP Basic Provisions should be defined (either added in each of the applicable Basic Provisions as a definition or included in the applicable section of each of the applicable Basic Provisions). The commenters stated this is important to define as reinstatement should not allow or require new applications to be submitted after the sales closing date, but limit reinstatement to the coverage that was terminated for which there would already be an application form on file. Allowing or requiring a new application to reinstate coverage is not necessary and could imply that changes to the coverage that was terminated is acceptable which would create a disproportionate benefit to those for whom coverage is reinstated. The commenters recommended "reinstatement" be defined as "Reinstatement of coverage will be limited to the coverage you had in place on the sales closing date for the crops that were terminated due to ineligibility for debt. No new application is required and no requests to change coverage level, change plans of insurance or add or remove options or endorsements will be accepted unless such changes were made and submitted on an application form on or prior to the sales closing date for the crop."

Response: FCIC agrees that the applicable provisions should clarify that reinstatement is under the same terms and conditions of the policy in effect as of the date termination became effective. Currently procedures published at *http://www.rma.usda.gov/bulletins/pm/2015/15-010a.pdf* make this clear. However, a definition of "reinstatement" has been added to subpart U because it is applicable to ineligibility determinations, appeals, and reinstatement requests and cross references have been added to section 2(k)(2)(iii)(B)(*3*)(*i*) of the ARPI Basic Provisions and section 2(f)(2)(iii)(B)(*3*)(*i*) of the CCIP Basic Provisions.

Comment: A commenter questioned how is an approved insurance provider going to determine whether a policyholders failure to pay premium was inadvertent in section 2(k)(2)(iii)(C)(*1*)(*i*) of the ARPI Basic Provisions and section 2(f)(2)(iii)(C)(*1*)(*i*) of the CCIP Basic Provisions.

Response: On February 24, 2015, FCIC issued information memorandum PM–15–010 Late Payment of Debt procedures found at *http://www.rma.usda.gov/bulletins/pm/2015/15-010a.pdf.* The criteria to qualify for an approved insurance provider authorized reinstatement can be found in section 2, paragraph 2 of these procedures. Those procedures have been modified to clarify the specific conditions that approved insurance providers are required to use in making the determination. The approved insurance providers must use the requirements in section 2(f)(2)(iii)(C)(*1*) of the CCIP and section 2(k)(2)(iii)(C)(*1*) of the ARPI Basic Provisions to make this determination. Additionally, on June 30, 2015, FCIC issued the General Standards Handbook, which can be found at *http://www.rma.usda.gov/handbooks/18000/* to further clarify the criteria an approved insurance provider is required to use in making a determination. No change has been made.

Comment: A commenter recommended FCIC move the current section 2(f)(2)(iii)(B)(*3*)(*ii*) of the CCIP Basic Provisions to be new a new section 2(f)(2)(iii)(B)(*3*) of the CCIP Basic Provisions, and combine the current sections 2(f)(2)(iii)(B)(*3*)(*i*) and 2(f)(2)(iii)(B)(*3*) of the CCIP Basic Provisions as a new section 2(f)(2)(iii)(B)(*4*) of the CCIP Basic Provisions. This organizational change sets the requirement that "there is no evidence of fraud or misrepresentation" apart from other text and appropriately makes it a key criteria for the Administrator granting reinstatement.

Response: FCIC disagrees with the commenter that the change provides improved organizational benefits to the extent that a change is warranted. The proposed changes may have adverse or unintended consequences. The proposed revision introduces new paragraph designations that are not necessary and may create the potential for additional cross-references that can lead to greater confusion and potential for inaccurate reading. No change has been made.

Comment: A commenter recommended FCIC revise section 2(f)(2)(iii)(C)(*1*)(*iii*) of the CCIP Basic Provisions as follows: "You timely made the full payment of the amount owed but the delivery of that payment was delayed, and was postmarked no more than 7 calendar days. . ." This change will clarify that this clause only provides an allowance for reinstatement following termination for a late postmarked payment; it does not allow the payment itself to be made late (*e.g.,* a late-dated check).

Response: FCIC agrees with the commenter and has revised the provisions accordingly.

Comment: A commenter stated section 2(f)(2)(iii)(C)(*3*) of the CCIP Basic Provisions requires the insured to submit a written request for reinstatement by the approved insurance provider in the situations indicated in sections 2(f)(2)(iii)(C)(*1*)(*i*) through (*iii*). The commenter believed the insured should only be required to submit a formal written request for sections 2(f)(2)(iii)(C)(*1*)(*i*) and (*ii*); the insured should not have to submit a written request for section 2(f)(2)(iii)(C)(*1*)(*iii*). For section 2(f)(2)(iii)(C)(*1*)(*iii*), the insured's full payment of the premium owed should serve as the payment and an implicit request for reinstatement. For any such late payment, the insured will not know at the time the check is mailed that the payment would be delayed in postal processing which resulted in policy termination. For reinstatements under section 2(f)(2)(iii)(C)(*1*)(*iii*), the approved insurance provider will verify the insured made a timely and full payment. This approach would eliminate any need for the insured to complete a form before an approved insurance provider can accept a payment that was postmarked late.

Response: FCIC issued procedures, which can be found at *http://www.rma.usda.gov/handbooks/18000/,* provide the approved insurance providers the guidance and direction that satisfy the written request requirement of 2(f)(2)(iii)(C)(*1*)(*iii*). No change has been made.

Comment: A commenter suggested that the language in current section 2(f)(2)(iii)(B)(*3*)(*i*) of the CCIP Basic Provisions also be included in section 2(f)(2)(iii)(C) of the CCIP Basic Provisions. It should be clear that reinstatement, whether granted by the Administrator or an approved insurance provider, is effective at the beginning of the crop year for which this insured was determined to be ineligible.

Response: FCIC agrees and has added the same language from section 2(f)(2)(iii)(B)(*3*)(*i*) of the CCIP Basic Provisions in a new section 2(f)(2)(iii)(C)(*4*) of the CCIP Basic Provisions. FCIC has made the same change in a new section 2(k)(2)(iii)(C)(*4*) of the ARPI Basic Provisions.

Comment: A commenter stated to make the policy clear concerning the specific administrative remedies the insured is waiving, as well as to ensure the insured understands they are waiving all other administrative remedies for any reinstatement request under these provisions, the commenter recommended FCIC replace section 2(f)(2)(iv) of the CCIP Basic Provisions as follows: "You may not commence litigation or arbitration against us, obtain an administrative review in accordance with 7 CFR part 400, subpart J (administrative review), or file an appeal in accordance with 7 CFR part 11 (appeal), with respect to any determination made under section 2(f)(2)(iii)(B) or section 2(f)(2)(iii)(C)."

Response: FCIC disagrees with the commenter. Section 20 of the CCIP Basic Provisions states that if the insured and the approved insurance provider fail to agree, the insured has a right to commence litigation, arbitration, administrative review, or file an appeal against the approved insurance provider. A determination made under section 2(f)(2)(iii)(B) or section 2(f)(2)(iii)(C) of the CCIP Basic Provisions is consistent with those for which the insured has a right to pursue appeal or other recourse. FCIC has revised the provisions to clarify that determinations made by the Administrator are only appealable to National Appeals Division, and determinations made by the approved insurance provider are appealable through the arbitration process in section 20 of the CCIP Basic Provisions.

Comment: A commenter stated it is unclear from section 2(f)(2)(iv) of the CCIP Basic Provisions if an insured still has the right to appeal a determination made by RMA under section 2(f)(2)(iii)(B) to USDA's National Appeals Division. RMA's draft procedures on this section stated that appeals to the National Appeals Division were not allowed. However, the commenter believed it is questionable whether FCIC has the authority to completely prohibit insured's from appealing these determinations to the National Appeals Division. Additionally, FCIC needs to clarify that requests for reinstatements made by approved insurance providers under section 2(f)(2)(iii)(C) are not subject to arbitration. Ultimately, only RMA has the power to reinstate a policy that has been terminated, even if the request is being made by the approved insurance provider under section 2(f)(iii)(C); therefore, these determinations should not be subject to arbitration.

If National Appeals Division appeals are precluded, the commenter recommended revising section 2(f)(2)(iv) to read as follows: "You may not commence litigation or arbitration against us, obtain an administrative review in accordance with 7 CFR part 400, subpart J (administrative review), or file an appeal in accordance with 7 CFR part 11 (appeal), with respect to any determination made under section 2(f)(2)(iii)(B) or section 2(f)(2)(iii)(C)."

If National Appeals Division appeals are allowed, the commenter recommended revising section 2(f)(2)(iv) to read as follows: "Determinations made under section 2(f)(2)(iii)(B) or section 2(f)(2)(iii)(C) may only be appealed in accordance with 7 CFR part 11 (appeal). You may not commence litigation or arbitration against us, or obtain an administrative review in accordance with 7 CFR part 400, subpart J (administrative review), with respect to any determination made under section 2(f)(2)(iii)(B) or section 2(f)(2)(iii)(C)."

Response: FCIC agrees that section 2(f)(2)(iv) is ambiguous and it was only intended to preclude requests for reconsideration under 7 CFR part 400, subpart J. It was never intended to preclude an appeal to the National Appeals Division. Further, producers have the right to appeal determinations by approved insurance providers under section 20 of the CCIP Basic Provisions. The provisions have been revised accordingly.

Comment: A commenter stated the interim rule narrative item 4.g. (**Federal Register** page 37161) indicates that removal of the phrase ", or any portion thereof," from current section 24(a) of the CCIP Basic Provisions is intended ". . . to remove ambiguity of the billing process and interest situations on amounts owed, and to ensure consistency in how insurance providers administer this section." The commenter does not believe this change clarifies how interest is to accrue. For example, if the insured does not pay premium for a crop with a 7/31 billing date until 9/15, under the 2014 provisions the insured could be assessed two months interest for the period of August and September. Absent the clause in 24(a), it is now unclear whether the insured would owe interest for any portion of the month of September. Any change to current billing practices could impact approved insurance providers ability to recoup debt collection costs for the insured's late payment when full premium payment was timely made to FCIC on behalf of the insured. The commenter questioned if this phrase should be removed.

A commenter stated for the 2015 reinsurance year, FCIC continues to issue Special Provision statement number 01282, which states "In lieu of the second sentence of Section 24(a) of the Basic Provisions, for the purpose of premium amounts owed to us or administrative fees owed to FCIC, interest will start to accrue on the first day of the month following the issuance of the notice by us, provided that a minimum of 30 days have passed from the premium billing date specified in the Special Provisions." The interim rule does not change the second sentence of 24(a). The commenter did not see a reason why this Special Provision statement could not be incorporated into the interim rule and the Special Provision statement be discontinued. However, the commenter noted that for the February 1 billing date the added provision of a minimum of 30 days does not work as there are only 28 or 29 days in the month of February. FCIC should therefore consider changing this to 28 days.

However, instead of the two changes suggested above by the commenter, ambiguity as to the precise amount of interest owed on unpaid premium billings could be eliminated by replacing the second sentence of 24(a) with the following language, which is modeled on 24(b): "For the purpose of premium amounts owed to us or administrative fees owed to FCIC, interest will start to accrue on the date that notice is issued to you for the collection of the unpaid amount. Amounts found due under this paragraph will not be charged interest if payment is made within 30 days of issuance of the notice by us." This change not only standardizes basic provision policy language, it is also consistent with revisions to section 6(b) of the CAT Endorsement and ensures premium billing is administered uniformly because interest accrues on a daily basis for all amounts owed.

Response: Interest is accrued on a monthly basis, not daily. For example, the billing date is July 1 and the due date for payment is July 31. Interest will be included on the next bill dated August 1 if the payment is not made on or before July 31, 30 days after the notice has been issued to the policyholder. If the producer pays their bill on September 15, they are only billed interest for July and August. The interest for the month of September has not yet accrued and therefore would not be owed or included in the amount due. Because interest accrues on a monthly basis the phrase ", or any portion thereof," is not needed. No change has been made. FCIC agrees with the commenter's suggestion to incorporate Special Provisions Statement 01282 into the policy language and has revised the language accordingly.

Comment: A commenter stated the interim rule removes the phrase ", or any portion thereof,". However, the Farm Bill Amendment posted to RMA's Web site did not remove the word "or". The revised section 24(a) of the CCIP Basic Provisions in RMA's Farm Bill Amendment should read: "Interest will accrue at the rate of 1.25 percent simple interest per calendar month or on any unpaid amount owed to us or on any unpaid administrative fees owed to FCIC . . ."

Response: The Farm Bill Amendment published on RMA's Web site contained an error and did not remove the word "or." However, the interim rule provided the correct language and the word "or" was removed in the regulation. FCIC will make this correction when the amendment for this final rule is issued.

Comment: A commenter stated the interim rule indicates the phrase ", or any part thereof," was removed from 24(b) for FCIC policies. The commenter was unaware of any Federal crop insurance policy regulation specific to "FCIC policies" and there is no such phrase in CCIP 24(b). The commenter stated FCIC should remove this item from the interim rule.

Response: For certain portions of the policy, FCIC maintains separate sections "for Reinsured Policies" and "FCIC Policies" in the Code of Federal Regulations. While no FCIC Policies are currently written, the authority to write such policies still exists and if there comes a time when such policies are needed, FCIC needs the provisions to enable it to provide such policies. Information regarding FCIC policies is only contained in the Code of Federal Regulations and is not included in the typeset policies published on the RMA Web site. Therefore, no change has been made.

Comment: A commenter stated the time limit set-forth in § 400.682(g) should be revised. An insured will always receive a notice of the amount due well before the policy is terminated and this 60 day period could potentially expire before the policy is terminated. Thus, the 60 day period should not be tied to a notice of debt. Also, until the insured receives notice that the policy has been terminated, there would really be no need for the insured to move forward with requesting relief from RMA. Therefore, we think a fairer and clearer approach to this issue would be to shorten the time period to 30 days; however, the 30 days would not begin to accrue until the insured receives notice that the policy has been terminated. The revised language would read as follows:

(3) No later than 30 days from the date of the notice from the FCIC informing the person of ineligibility due to nonpayment of a debt, the ineligible person may request consideration for reinstatement from the Administrator of the Risk Management Agency in accordance with section 2 of the CCIP Basic Provisions (7 CFR 457.8).

Response: FCIC agrees that as written, the language in § 400.682(g) can be confusing and requires further clarification. The phrase "the due date specified in the notice to the person of the amount due" could be interpreted to apply to different types of scenarios and/or notices, *i.e.* billing statements. FCIC intended for this phrase to only apply in situations where the insured has received notice of an amount due after the termination date (for example, an overpaid indemnity or when premium revisions occur requiring additional premium be owed and billed), meaning the ineligible person may request consideration for reinstatement no later than 60 days after the due date specified in the notice of overpaid indemnity, additional premium owed due to revisions, or any other amounts due after the termination date. FCIC has revised § 400.682(g) to state the 60-day time period starts on the due date specified in the notice to the person of the amount due in the case of an overpaid indemnity or any other amount that becomes due after the termination date. FCIC has also made the same change in the ARPI Basic Provisions and CCIP Basic Provisions.

Comment: A commenter stated the time limit set-forth in section 2(f)(2)(iii)(B)(*3*) of the CCIP Basic Provisions should be revised. An insured will always receive a notice of the amount due well before the policy is terminated and this 60 day period could potentially expire before the policy is terminated. Thus, the 60 day period should not be tied to a notice of debt. Also, until the insured receives notice that the policy has been terminated, there would really be no need for the insured to move forward with requesting reinstatement from RMA. Therefore, the commenter thought a fairer and clearer approach to this issue would be to shorten the time period to 30 days; however the 30 days would not begin to accrue until the insured receives notice that the policy has been terminated. The revised language would read as follows:

You submit a written request for reinstatement of your policy to us no later than 30 days from the date of the notice from the FCIC informing you of your ineligibility due to nonpayment of a debt.

The commenter stated the same comment above about the time limit for these requests that applies to section 2(f)(2)(iii)(C) of the CCIP Basic Provisions. Additionally, it makes no sense to apply the written request requirement to late postmarks that fall within the 7 day transit period. These should just be automatically reinstated by the approved insurance providers. An Appendix III code should be developed so that policies which fit these criteria are tracked, but are never actually terminated and made ineligible in the first instance. As revised, this section would read as follows:

(C) We determine that, in accordance with 7 CFR part 400, subpart U and FCIC issued procedures, one of the following two conditions are met:

(1) You submit a written request for reinstatement of your policy to us in accordance with 7 CFR part 400, subpart U and applicable procedures no later than 30 days after the termination date or the missed payment date of a previously executed written payment agreement, or the due date specified in the notice to you of the amount due, if applicable, in which you demonstrate that:

(i) You made timely payment for the amount of premium owed but you inadvertently omitted some small amount, such as the most recent month's interest or a small administrative fee or the amount of the payment was clearly transposed from the amount that was otherwise due (For example, you owed $832 but you paid $823);

(ii) You remit full payment of the delinquent debt owed to us with your request for reinstatement; and

(iii) There is no evidence of fraud or misrepresentation; or

(2) You sent the full payment to us by mail and the payment was postmarked after the termination date or other applicable due date, but received by us within 7 calendar days after the termination date or other applicable due date.

Response: As stated above, FCIC agrees that as written, the language regarding the 60 day period can be confusing and requires further clarification. FCIC has revised section 2(f)(2)(iii) of the CCIP Basic Provisions and section 2(k)(2)(iii) of the ARPI Basic Provisions to state the 60 days starts on the due date specified in the notice to the person of the amount due in the case of an overpaid indemnity or any other amount that becomes due after the termination date. Lastly, FCIC has revised the reference to "$832 but you paid $823" in section 2(f)(2)(iii)(C)(*1*)(*ii*) of the CCIP Basic Provisions to "$892 but you paid $829" for clarity and consistency purposes in accordance with Appendix III to the Standard Reinsurance Agreement and instructions for handling debt and ineligibility. Appendix III of the Standard Reinsurance Agreement allows approved insurance providers the latitude to write-off balances equal to or less than $50. Therefore, the example has been revised to reflect a difference of greater than $50.

In addition to the changes described above, FCIC has revised the definition of "approved yield" to clarify the approved yield may have yield exclusions elected under section 5 of the CCIP Basic Provisions. The definition listed exceptions or adjustments that may be made to an approved yield. Section 5, which addresses exclusion of yields should be included in this list.

FCIC has also revised the provisions in section 34(a)(5)(i)(A)(*3*) of the CCIP Basic Provisions. The requirement to allow separate units by irrigated and non-irrigated practice were added to enterprise units in the interim rule. FCIC inadvertently omitted allowing separate units by irrigated and non-irrigated practices for whole-farm units. FCIC published a Special Provisions statement to allow such and has incorporated this change in the final rule and will remove the Special Provisions statement after this final rule is published.

Effective Date

The Administrative Procedure Act (5 U.S.C. 553) provides generally that before rules are issued by Government agencies, the rule is required to be published in the **Federal Register**, and the required publication of a substantive rule is to be not less than 30 days before its effective date. One of the exceptions is when the agency finds good cause for not delaying the effective date. Delaying the effective of this rule would result in the inability of the Federal Government to implement these changes prior to the contract change date for fall planted crops, effectively delaying their implementation for an entire year. Therefore, using the administrative procedure provisions in 5 U.S.C. 553, RMA finds that there is good cause for making this rule effective less than 30 days after publication in the **Federal Register**. This rule allows RMA to make the changes to the General Administrative Regulations; Catastrophic Risk Protection Endorsement; Area Risk Protection Insurance Regulations; and the Common Crop Insurance Regulations, Basic Provisions in time for 2017 fall planted crops. Therefore, this final rule is effective when published in the **Federal Register**.

Executive Order 12866

This rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, it has been reviewed by the Office of Management and Budget (OMB).

Benefit-Cost Analysis

A Benefit-Cost Analysis (BCA) has been completed and a summary is shown below; the full analysis may be viewed on *http://www.regulations.gov* in the docket listed above. In summary, the analysis finds that changes in the rule will have an expected cost to FCIC of $115.9 million annually over a 10-year period in administration of the Federal crop insurance program. Non-quantifiable benefits of this rule include increased program integrity, additional risk management tools for producers, and incentives for beginning farmers and ranchers to participate in the Federal crop insurance program.

On February 7, 2014, the 2014 Farm Bill was enacted. As a result, FCIC revised those provisions of the General Administrative Regulations—Ineligibility for Programs under the Federal Crop Insurance Act (subpart U), Catastrophic Risk Protection Endorsement (CAT Endorsement), Area Risk Protection Insurance (ARPI) Basic Provisions, and the Common Crop Insurance Provisions (CCIP) Basic Provisions to timely implement program changes identified in Titles II and XI of the 2014 Farm Bill.

On January 2014, the Congressional Budget Office (CBO) issued its estimates for the effects on direct spending and revenues of the 2014 Farm Bill. These estimates were used as a basis for the quantifiable costs and benefits stated in this BCA.

The purpose of this rule is to amend subpart U, the CAT Endorsement, the ARPI Basic Provisions, and the CCIP Basic Provisions to implement the following changes:

Section 2611 requires those enrolled in Federal crop insurance, for certain agriculture commodities, to comply with conservation compliance requirements or forego premium subsidy. For acts or situations of non-compliance, ineligibility for premium subsidy will be applied beginning with the 2016 reinsurance year. Annually, FCIC anticipates a savings of $4.6 million as a result of this change.

Section 11007 makes available insurance coverage by separate enterprise units based on irrigated and non-irrigated acreage of a crop within a county. Annually, FCIC anticipates a cost of $53.3 million as a result of this change.

Section 11009 allows insureds to exclude any recorded or appraised yield for any crop year in which the per planted acre yield in the county is at least 50 percent below the simple average per planted acre yield for the crop in the county for the previous 10 consecutive crop years, and allows insureds in any county contiguous to a county in which an insured is eligible to exclude a recorded or appraised yield to also elect a similar adjustment. Annually, FCIC anticipates a cost of $35.7 million as a result of this change.

Section 11014 applies a reduction of premium subsidy, a reduced insurance guarantee, and eliminates substitute yields in the insurance guarantee during the first four crop years that land is converted from native sod to the production of an annual crop in the States of Iowa, Minnesota, Montana, Nebraska, North Dakota, and South Dakota. Annually, FCIC anticipates a savings of $11.4 million as a result of this change.

Section 11015 allows producers to elect a different level of coverage for an agricultural commodity by irrigated and non-irrigated acreage. Annually, FCIC anticipates a cost of $16.8 million as a result of this change.

Section 11016 establishes crop insurance benefits for beginning farmers and ranchers by increasing the premium subsidy available by ten percentage points, allowing the use of yield history from any previous farm or ranch operation in which they had decision making or physical involvement, and replacing a low yield in their actual production history (APH) with a yield equal to 80 percent of the applicable transitional yield. Annually, FCIC anticipates a cost of $26.1 million as a result of this change.

Section 11019 allows for the correction of errors in information obtained from the producer within a reasonable amount of time and consistent with information provided by the producer to other agencies of the Department of Agriculture subject to certain limitations for maintaining program integrity. This section also provides for the payment of debt after the termination date in accordance with procedures and limitations established by the FCIC, if a producer inadvertently fails to pay a debt and has been determined to be ineligible to participate in the Federal crop insurance program. FCIC does not believe there are any additional cost outlays resulting from this change. Therefore, FCIC believes some insureds will benefit from this change and the benefits are non-quantifiable.

Paperwork Reduction Act of 1995

Pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved by OMB under control numbers 0563–0085, 0563–0083, and 0563–0053.

E-Government Act Compliance

FCIC is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Federal Crop Insurance Corporation has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Federal Crop Insurance Corporation will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Regulatory Flexibility Act

FCIC certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Program requirements for the Federal crop insurance program are the same for all producers regardless of the size of their farming operation. For instance, all producers are required to submit an application and acreage report to establish their insurance guarantees and compute premium amounts, and all producers are required to submit a notice of loss and production information to determine the amount of an indemnity payment in the event of an insured cause of crop loss. Whether a producer has 10 acres or 1000 acres, there is no difference in the kind of information collected. To ensure crop insurance is available to small entities, the Federal Crop Insurance Act (Act) authorizes FCIC to waive collection of administrative fees from beginning farmers or ranchers and limited resource farmers. FCIC believes this waiver helps to ensure that small entities are given the same opportunities as large entities to manage their risks through the use of Federal crop insurance. A Regulatory Flexibility Analysis has not been prepared since this regulation does not have an impact on small entities, and, therefore, this regulation is exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605).

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or to require the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11 must be exhausted before any action against FCIC for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, or safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

List of Subjects in 7 CFR Parts 400, 402, 407 and 457

Administrative practice and procedure, Crop insurance, Reporting and recordkeeping requirements.

Final Rule

Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation adopts as final the interim rule amending 7 CFR parts 400, 402, 407, and 457, published at 79 FR 37155 on July 1, 2014, as final with the following changes:

PART 400—GENERAL ADMINISTRATIVE REGULATIONS

■ 1. The authority citation is added for 7 CFR part 400 to read as follows:

Authority: 7 U.S.C. 1506(1), 1506(o).

■ 2. Amend § 400.677 by adding the definition of "reinstatement" in alphabetical order to read as follows:

§ 400.677 Definitions.

* * * * *

Reinstatement means that the policy will retain the same plan of insurance, coverage levels, price percentages, endorsements and options the person had prior to termination, provided the person continues to meet all eligibility requirements, comply with the terms of the policy, and there is no evidence of misrepresentation or fraud.

* * * * *

■ 3. Amend § 400.679 as follows:

■ a. In paragraph (e) by adding a semicolon at the end of the paragraph; and

■ b. Revising paragraph (g).

The revision reads as follows:

§ 400.679 Criteria for ineligibility.

* * * * *

(g) Has requested the Administrator, Risk Management Agency, for consideration to reinstate their eligibility in accordance with the applicable policy provisions and such request has been denied.

■ 4. Amend § 400.682 by revising paragraph (g) to read as follows:

§ 400.682 Determination and notification.

* * * * *

(g) No later than 60 days after the termination date, a missed payment date of a previously executed written payment agreement, or in the case of an overpaid indemnity or any amount that became due after the termination date, the due date specified in a notice to the person of an amount due, as applicable, such ineligible person may request consideration for reinstatement from the Administrator, Risk Management Agency, in accordance with section 2 of the Common Crop Insurance Policy Basic Provisions (7 CFR 457.8).

PART 402—CATASTROPHIC RISK PROTECTION ENDORSEMENT

■ 5. The authority citation for 7 CFR part 402 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(o).

■ 6. Amend § 402.4 as follows:

■ a. In section 3(c) by removing the phrase "paragraph (b) above" and adding in its place the phrase "section 3(b)";

■ b. In section 6(a) by removing the phrase "paragraphs (f) and (h) of this section" and adding in its place the phrase "sections 6(f) and (h)";

■ c. In section 6(b) by removing the phrase "paragraph (f) of this section" and adding in its place the phrase "section 6(f)";

■ d. In section 6(c) by removing the phrase "paragraph (b) of this section" and adding in its place the phrase "section 6(b)";

■ e. In section 6(d) by removing the phrase "paragraph (b) of this section" and adding in its place the phrase "section 6(b)";

■ f. In section 6(e) by removing the phrase "paragraph (f) of this section" and adding in its place the phrase "section 6(f)";

■ g. In section 6(f)(2) by removing the phrase "paragraph (f)(1) of this section" and adding in its place the phrase "section 6(f)(1)";

■ h. Revise section 6(f)(2)(i);

■ i. In section 6(f)(2)(ii)(A) by removing the phrase "paragraph (f)(1) of this section" and adding in its place the phrase "section 6(f)(1)";

■ j. In section 6(f)(2)(ii)(B) by removing the phrase "paragraph (f)(1) of this section" and adding in its place the phrase "section 6(f)(1)"; and

■ k. In section 6(h) by removing the phrase "paragraph (f) of this section" and adding in its place the phrase "section 6(f)".

The revision reads as follows:

§ 402.4 Catastrophic Risk Protection Endorsement Provisions.

* * * * *

6. Annual Premium and Administrative Fees

* * * * *

(f) * * *

(2) * * *

(i) Notwithstanding section 6(f)(2), if you demonstrate you began farming for the first time after June 1 but prior to the beginning of the reinsurance year (July 1), you may be eligible for premium subsidy the subsequent reinsurance year without having form AD–1026 on file with FSA on or before June 1. For example, if you demonstrate you started farming for the first time on June 15, 2015, you may be eligible for premium subsidy for the 2016 reinsurance year without form AD–1026 on file with FSA.

* * * * *

PART 407—AREA RISK PROTECTION INSURANCE REGULATIONS

■ 7. The authority citation for 7 CFR part 407 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(o).

■ 8. Amend § 407.9 as follows:

■ a. In section 1 by revising the definition of "beginning farmer or rancher";

■ b. Revise sections 2(k)(2)(iii) and (iv);

■ c. Revise section 5(d);

■ d. In section 5(e) by removing the phrase "areas of" and adding in its place the word "cumulative";

■ e. Revise section 7(i)(2)(i);

■ f. In section 22(b) [FCIC policies] by adding the phrase "the issuance of the notice by us, provided that a minimum of 30 days have passed from" after the phrase "interest will start to accrue on the first day of the month following";

■ g. In section 22(a)(1) [Reinsured policies] by adding the phrase "the issuance of the notice by us, provided that a minimum of 30 days have passed from" after the phrase "interest will start to accrue on the first day of the month following"; and

■ h. In section 31(a)(1) by removing the word "the" after the phrase "any person with a substantial beneficial interest in".

The revisions read as follows:

§ 407.9 Area risk protection insurance policy.

* * * * *

1. Definitions

* * * * *

Beginning farmer or rancher. An individual who has not actively operated and managed a farm or ranch in any state, with an insurable interest in a crop or livestock as an owner-operator, landlord, tenant, or sharecropper for more than five crop years, as determined in accordance with FCIC procedures. Any crop year's insurable interest may, at your election, be excluded if earned while under the age of 18, while in full-time military service of the United States, or while in post-secondary education, in accordance with FCIC procedures. A person other than an individual may be eligible for beginning farmer or rancher benefits if there is at least one individual substantial beneficial interest holder and all individual substantial beneficial interest holders qualify as a beginning farmer or rancher.

* * * * *

2. Life of Policy, Cancellation, and Termination

* * * * *

(k) * * *

(2) * * *

(iii) Once the policy is terminated, it cannot be reinstated for the current crop year unless:

(A) The termination was in error;

(B) The Administrator of the Risk Management Agency, at his or her sole discretion, determines that the following conditions are met:

(*1*) In accordance with 7 CFR part 400, subpart U, and FCIC issued procedures, you provide documentation that your failure to pay your debt is due to an unforeseen or unavoidable event or an extraordinary weather event that created an impossible situation for you to make timely payment;

(*2*) You remit full payment of the delinquent debt owed to us or FCIC with your request submitted in accordance with section 2(k)(2)(iii)(B)(*3*); and

(*3*) You submit a written request for reinstatement of your policy to us no later than 60 days after the termination date or the missed payment date of a previously executed written payment agreement, or in the case of overpaid indemnity or any amount that became due after the termination date, the due date specified in the notice to you of the amount due, if applicable.

(*i*) If authorization for reinstatement, as defined in 7 CFR part 400, subpart U, is granted, your policies will be reinstated effective at the beginning of the crop year for which you were determined ineligible, and you will be entitled to all applicable benefits under such policies, provided you meet all eligibility requirements and comply with the terms of the policy; and

(*ii*) There is no evidence of fraud or misrepresentation; or

(C) We determine that, in accordance with 7 CFR part 400, subpart U, and FCIC issued procedures, the following are met:

(*1*) You can demonstrate:

(*i*) You made timely payment for the amount of premium owed but you inadvertently omitted some small amount, such as the most recent month's interest or a small administrative fee;

(*ii*) The amount of the payment was clearly transposed from the amount that was otherwise due (For example, you owed $892 but you paid $829); or

(*iii*) You timely made the full payment of the amount owed but the delivery of that payment was delayed, and was postmarked no more than seven calendar days after the termination date or the missed payment date of a previously executed written payment agreement, or in the case of overpaid indemnity or any amount that became due after the termination date, the due date specified in a notice to you of an amount due, as applicable;

(*2*) You remit full payment of the delinquent debt owed to us; and

(*3*) You submit a written request for reinstatement of your policy to us in accordance with 7 CFR part 400, subpart U, and applicable procedures no later than 30 days after the termination date or the missed payment date of a previously executed written payment agreement, or in the case of overpaid indemnity or any amount that became due after the termination date, the due date specified in the notice to you of the amount due, if applicable; and

(*4*) If authorization for reinstatement, as defined in 7 CFR part 400, subpart U, is granted, your policies will be reinstated effective at the beginning of the crop year for which you were determined ineligible, and you will be entitled to all applicable benefits under such policies, provided you meet all eligibility requirements and comply with the terms of the policy; and

(*5*) There is no evidence of fraud or misrepresentation.

(iv) A determination made under:

(A) Section 2(k)(2)(iii)(B) may only be appealed to the National Appeals Division in accordance with 7 CFR part 11; and

(B) Section 2(k)(2)(iii)(C) may only be appealed in accordance with section 23.

* * * * *

5. Insurable Acreage

* * * * *

(d) Except as provided in section 5(e), in the states of Iowa, Minnesota, Montana, Nebraska, North Dakota, and South Dakota, during the first four crop years of planting on native sod acreage that has been tilled after February 7, 2014, such acreage may be insured if the requirements of section 5(a) have been met but will:

(1) Notwithstanding the provisions in section 6, receive a liability that is based on 65 percent of the protection factor; and

(2) For additional coverage policies, receive a premium subsidy that is 50 percentage points less than would otherwise be provided on acreage not qualifying as native sod. If the premium subsidy applicable to these acres is less than 50 percent before the reduction, you will receive no premium subsidy.

* * * * *

7. Annual Premium and Administrative Fees

* * * * *

(i) * * *

(2) * * *

(i) Notwithstanding section 7(i)(2), if you demonstrate you began farming for the first time after June 1 but prior to the beginning of the reinsurance year (July 1), you may be eligible for premium subsidy the subsequent reinsurance year without having form AD–1026 on file with FSA on or before June 1. For example, if you demonstrate you started farming for the first time on June 15, 2015, you may be eligible for premium subsidy for the 2016 reinsurance year without form AD–1026 on file with FSA.

* * * * *

PART 457—COMMON CROP INSURANCE REGULATIONS

■ 9. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

■ 10. Amend § 457.8, in the Common Crop Insurance Policy, as follows:

■ a. In section 1 by revising the definitions of "approved yield", "beginning farmer or rancher", and "enterprise unit";

■ b. Revise sections 2(f)(2)(iii) and (iv);

■ c. In section 5 by removing the phrase "per acre planted" and adding in its place the phrase "per planted acre";

■ d. Revise section 7(h)(2)(i);

■ e. In section 9(e) by removing the phrase "and is planted to an annual crop";

■ f. In section 9(f) by removing the phrase "areas of" and adding in its place the word "cumulative";

■ g. Under "For FCIC policies", in section 24(b), by adding the phrase "the issuance of the notice by us, provided that a minimum of 30 days have passed from" after the phrase "interest will start to accrue on the first day of the month following";

■ h. Under "For reinsured policies", in section 24(a), by adding the phrase "the issuance of the notice by us, provided that a minimum of 30 days have passed from" after the phrase "interest will start to accrue on the first day of the month following";

■ i. In section 25(a)(1) by removing the word "the" after the phrase "any person with a substantial beneficial interest in";

■ j. Revise section 34(a)(5)(i)(A)(*3*); and

■ k. In section 36(c) by adding a comma after the phrase "unless you qualify as a beginning farmer or rancher".

The revisions read as follows:

§ 457.8 The application and policy.

* * * * *

Common Crop Insurance Policy

* * * * *

1. Definitions

* * * * *

Approved yield. The actual production history (APH) yield, calculated and approved by the verifier, used to determine the production guarantee by summing the yearly actual, assigned, adjusted or unadjusted transitional yields and dividing the sum by the number of yields contained in the database, which will always contain at least four yields. The database may contain up to 10 consecutive crop years of actual or assigned yields. The approved yield may have yield exclusions elected under section 5, yield adjustments elected under section 36, revisions according to section 3, or other limitations according to FCIC approved procedures applied when calculating the approved yield.

* * * * *

Beginning farmer or rancher. An individual who has not actively operated and managed a farm or ranch in any state, with an insurable interest in a crop or livestock as an owner-operator, landlord, tenant, or sharecropper for more than five crop years, as determined in accordance with FCIC procedures. Any crop year's insurable interest may, at your election, be excluded if earned while under the age of 18, while in full-time military service of the United States, or while in post-secondary education, in accordance with FCIC procedures. A person other than an individual may be eligible for beginning farmer or rancher benefits if there is at least one individual substantial beneficial interest holder and all individual substantial beneficial interest holders qualify as a beginning farmer or rancher.

* * * * *

Enterprise unit. All insurable acreage of the same insured crop or all insurable irrigated or non-irrigated acreage of the same insured crop in the county in which you have a share on the date coverage begins for the crop year, provided the requirements of section 34 are met.

* * * * *

2. Life of Policy, Cancellation, and Termination

* * * * *

(f) * * *

(2) * * *

(iii) Once the policy is terminated, it cannot be reinstated for the current crop year unless:

(A) The termination was in error;

(B) The Administrator of the Risk Management Agency, at his or her sole discretion, determines that the following are met:

(*1*) In accordance with 7 CFR part 400, subpart U, and FCIC issued procedures, you provide documentation that your failure to pay your debt is due to an unforeseen or unavoidable event or an extraordinary weather event that created an impossible situation for you to make timely payment;

(*2*) You remit full payment of the delinquent debt owed to us or FCIC with your request submitted in accordance with section 2(f)(2)(iii)(B)(*3*); and

(*3*) You submit a written request for reinstatement of your policy to us no later than 60 days after the termination date or the missed payment date of a previously executed written payment agreement, or in the case of overpaid indemnity or any amount that became due after the termination date, the due date specified in the notice to you of the amount due, if applicable.

(*i*) If authorization for reinstatement, as defined in 7 CFR part 400, subpart U, is granted, your policies will be reinstated effective at the beginning of the crop year for which you were determined ineligible, and you will be entitled to all applicable benefits under such policies, provided you meet all eligibility requirements and comply with the terms of the policy; and

(*ii*) There is no evidence of fraud or misrepresentation; or

(C) We determine that, in accordance with 7 CFR part 400, subpart U, and FCIC issued procedures, the following are met:

(*1*) You can demonstrate:

(*i*) You made timely payment for the amount of premium owed but you inadvertently omitted some small amount, such as the most recent month's interest or a small administrative fee;

(*ii*) The amount of the payment was clearly transposed from the amount that was otherwise due (For example, you owed $892 but you paid $829); or

(*iii*) You timely made the full payment of the amount owed but the delivery of that payment was delayed, and was postmarked no more than seven calendar days after the termination date or the missed payment date of a previously executed written payment agreement, or in the case of overpaid indemnity or any amount that became due after the termination date, the due date specified in a notice to you of an amount due, as applicable.

(*2*) You remit full payment of the delinquent debt owed to us; and

(*3*) You submit a written request for reinstatement of your policy to us in accordance with 7 CFR part 400, subpart U, and applicable procedures no later than 30 days after the termination date or the missed payment date of a previously executed written payment agreement, or in the case of overpaid indemnity or any amount that became due after the termination date, the due date specified in the notice to you of the amount due, if applicable; and

(*4*) If authorization for reinstatement, as defined in 7 CFR part 400, subpart U, is granted, your policies will be reinstated effective at the beginning of the crop year for which you were determined ineligible, and you will be entitled to all applicable benefits under such policies, provided you meet all eligibility requirements and comply with the terms of the policy; and

(*5*) There is no evidence of fraud or misrepresentation.

(iv) A determination made under:

(A) Section 2(f)(2)(iii)(B) may only be appealed to the National Appeals Division in accordance with 7 CFR part 11; and

(B) Section 2(f)(2)(iii)(C) may only be appealed in accordance with section 20.

* * * * *

7. Annual Premium and Administrative Fees

* * * * *

(h) * * *

(2) * * *

(i) Notwithstanding section 7(h)(2), if you demonstrate you began farming for the first time after June 1 but prior to the beginning of the reinsurance year (July 1), you may be eligible for premium subsidy the subsequent reinsurance year without having form AD–1026 on file with FSA on or before June 1. For example, if you demonstrate you started farming for the first time on June 15, 2015, you may be eligible for premium subsidy for the 2016 reinsurance year without form AD–1026 on file with FSA.

* * * * *

34. Units

(a) * * *

(5) * * *

(i) * * *

(A) * * *

(*3*) At the same coverage level (*e.g.,* if you elect to insure your corn and canola at the 65 percent coverage level and your soybeans at the 75 percent coverage level, the corn, soybeans and canola would be assigned the unit structure in accordance with section 34(a)(5)(v)) unless you can elect separate coverage levels for all irrigated and all non-irrigated crops in accordance with section 3(b)(2)(iii) (*e.g.* if you elect to insure your irrigated corn at the 65 percent coverage level you must insure your irrigated canola at the 65 percent coverage level. If you elect to insure your non-irrigated corn at the 70 percent coverage level you must insure your non-irrigated canola at the 70 percent coverage level. If you elect to insure your irrigated corn at the 65 percent coverage level and your irrigated canola at the 70 percent coverage level your unit structure will be assigned in accordance with section 34(a)(5)(v));

* * * * *

Signed in Washington, DC, on June 23, 2016.

Brandon C. Willis,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 2016–15327 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA 2015 7491; Directorate Identifier 2015–NE–39–AD; Amendment 39–18569; AD 2016–13–05]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

Correction

In rule document 2016–14474, beginning on page 41208 in the issue of Friday, June 24, 2016, make the following correction:

§ 39.13 [Corrected]

On page 41210, in the table titled "Table 1 to Paragraph (e)—HPC Stage 8–10 Spool S/Ns", the first row of the table should appear as follows:

1844M90G01	GWN005MF	GWNBK753	GWNBS077	GWNBS497	GWNBS724
	GWN005MG	GWNBK754	GWNBS078	GWNBS499	GWNBS794
	GWN0087M	GWNBK841	GWNBS079	GWNBS500	GWNBS810
	GWN0087N	GWNBK842	GWNBS080	GWNBS501	GWNBS811
	GWN00DGK	GWNBK843	GWNBS081	GWNBS502	GWNBS812
	GWN00DGL	GWNBK844	GWNBS157	GWNBS609	GWNBS813
	GWNBJ992	GWNBK952	GWNBS158	GWNBS610	GWNBS814
	GWNBK667	GWNBK953	GWNBS159	GWNBS611	GWNBS910
	GWNBK674	GWNBK954	GWNBS160	GWNBS612	GWNBS911
	GWNBK675	GWNBK955	GWNBS266	GWNBS613	GWNBS912
	GWNBK743	GWNBK956	GWNBS267	GWNBS614	GWNBS914
	GWNBK744	GWNBK957	GWNBS268	GWNBS721	GWNBS915
	GWNBK751	GWNBK958	GWNBS269	GWNBS722	GWNBS982
	GWNBK752	GWNBK959	GWNBS270	GWNBS723	GWNBS983

[FR Doc. C1–2016–14474 Filed 6–29–16; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL TRADE COMMISSION

16 CFR Part 1

Adjustment of Civil Monetary Penalty Amounts

AGENCY: Federal Trade Commission.

ACTION: Interim final rule.

SUMMARY: Pursuant to the Federal Civil Penalties Inflation Adjustment Act, as amended, the Federal Trade Commission ("FTC" or "Commission") is increasing the maximum civil penalty amounts within its jurisdiction, as required by the Federal Civil Penalty Inflation Adjustment Act Improvements Act of 2015.

DATES: The interim final rule is effective August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Kenny A. Wright, Attorney, Office of the General Counsel, FTC, 600 Pennsylvania Avenue NW., Washington, DC 20580, (202) 326–2907, *kwright@ftc.gov.*

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 ("Adjustment Improvements Act" or "Act")[1] requires federal agencies to implement a "catch-up adjustment" in 2016 to address inflation since the civil penalties within their jurisdiction were last set or adjusted by statute. The law mandates that agencies perform this adjustment through an interim final rulemaking and it sets forth a specific methodology to calculate the adjustment. Following this initial catch-up adjustment, the Adjustment Improvements Act directs agencies to adjust their civil penalties for inflation every January thereafter.

Commission Rule 1.98 sets forth the maximum civil penalty amounts for violations of laws enforced by the Commission that authorize civil penalties.[2] These amounts reflect earlier adjustments under the Federal Civil Penalties Inflation Adjustment Act which mandated a different methodology than the Adjustment Improvements Act.

When the Commission seeks civil penalties, it is mindful of the statutory criteria courts must apply when determining the amount of the civil penalty: "the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require."[3] Courts determining penalty amounts for violations of a final order under the FTC Act have similarly applied a multi-factor test that looks at the good or bad faith of the respondent; the injury to the public; the respondent's ability to pay; the desire to eliminate the benefits derived from the violations; and the necessity of vindicating the Commission's authority.[4] The Commission also has a civil penalty leniency program for small businesses that establishes criteria the Commission will consider when determining the propriety of a penalty waiver or reduction for small businesses that are not in compliance with the law.[5]

As required by the Act, the following adjusted amounts will take effect on August 1, 2016:

- Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1) (premerger filing notification violations under the Hart-Scott-Rodino (HSR) Improvements Act)—Increase from $16,000 to $40,000;
- Section 11(*l*) of the Clayton Act, 15 U.S.C. 21(*l*) (violations of cease and desist orders issued under Clayton Act section 11(b))—Increase from $8,500 to $21,250;
- Section 5(*l*) of the FTC Act, 15 U.S.C. 45(*l*) (violations of final Commission orders issued under section 5(b) of the FTC Act)—Increase from $16,000 to $40,000;
- Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. 45(m)(1)(A) (unfair or deceptive acts or practices)—Increase from $16,000 to $40,000;
- Section 5(m)(1)(B) of the FTC Act, 15 U.S.C. 45(m)(1)(B) (unfair or deceptive acts or practices)—Increase from $16,000 to $40,000;
- Section 10 of the FTC Act, 15 U.S.C. 50 (failure to file required reports)—Increase from $210 to $525;
- Section 5 of the Webb-Pomerene (Export Trade) Act, 15 U.S.C. 65 (failure by associations engaged solely in export trade to file required statements)—Increase from $210 to $525;
- Section 6(b) of the Wool Products Labeling Act, 15 U.S.C. 68d(b) (failure by wool manufacturers to maintain required records)—Increase from $210 to $525;
- Section 3(e) of the Fur Products Labeling Act, 15 U.S.C. 69a(e)(failure to maintain required records regarding fur products)—Increase from $210 to $525;
- Section 8(d)(2) of the Fur Products Labeling Act, 15 U.S.C. 69f(d)(2) (failure to maintain required records regarding fur products)—Increase from $210 to $525;
- Section 333(a) of the Energy Policy and Conservation Act, 42 U.S.C. 6303(a) (knowing violations of EPCA § 332, including labeling violations)—Increase from $210 to $433;
- Section 525(a) of the Energy Policy and Conservation Act, 42 U.S.C. 6395(a) (recycled oil labeling violations)—Increase from $8,500 to $21,250;

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[1] Public Law 114–74, sec. 701, 129 Stat. 599 (2015). The Act amends the Federal Civil Penalties Inflation Adjustment Act ("FCPIAA"), Public Law 101–410, 104 Stat. 890 (codified at 28 U.S.C. 2461 note).

[2] 16 CFR 1.98.

[3] 15 U.S.C. 45(m)(1)(C). This standard applies to penalties for violations of Commission rules addressing unfair or deceptive practices issued under section 18 of the FTC Act, and to violations of other statutes that provide for civil penalties by reference to section 18.

[4] *United States* v. *Reader's Digest Ass'n,* 662 F.2d 955, 967 (3d Cir. 1981).

[5] 62 FR 16809 (Apr. 8, 1997), *https://www.gpo.gov/fdsys/pkg/FR-1997-04-08/pdf/97-8941.pdf.*

- Section 525(b) of the Energy Policy and Conservation Act, 42 U.S.C. 6395(b) (willful violations of recycled oil labeling requirements)—Increase from $16,000 to $40,000;
- Section 621(a)(2) of the Fair Credit Reporting Act, 15 U.S.C. 1681s(a)(2) (knowing violations of the Fair Credit Reporting Act)—Increase from $3,500 to $3,756;
- Section 1115(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108–173, 21 U.S.C. 355 note (failure to comply with filing requirements)—Increase from $12,100 to $14,142; and
- Section 814(a) of the Energy Independence and Security Act of 2007, 42 U.S.C. 17304 (violations of prohibitions on market manipulation and provision of false information to federal agencies)—Increase from $1,100,000 to $1,138,330.

Calculation of Inflation Adjustments

The Adjustment Improvements Act directs federal agencies to adjust the civil monetary penalties under their jurisdiction for inflation through an initial "catch-up" cost-of-living adjustment. This catch-up adjustment is defined as the percentage by which the U.S. Department of Labor's Consumer Price Index for all-urban consumers ("CPI–U") for the month of October 2015 exceeds the CPI–U for the month of October for the year in which the amount of the penalty was last set or adjusted pursuant to law, excluding prior adjustments under FCPIAA.[6] The Adjustment Improvements Act also directs that these penalty level adjustments should be rounded to the nearest dollar. The Act provides, however, that the amount of the catch-up increase for 2016 shall not exceed 150 percent of the amount of the civil penalty in effect on November 2, 2015.

Agencies do not have discretion over whether to make the initial catch-up adjustment for maximum civil penalty amounts absent a determination that the adjustment will have a negative economic impact or the social costs of the increase outweigh the benefits.[7] The Commission has determined that there is no basis to conclude that these inflationary adjustments of maximum civil penalty amounts will have such effects. Accordingly, the Commission is making these adjustments as mandated.

CALCULATION OF ADJUSTMENTS TO MAXIMUM CIVIL MONETARY PENALTIES

Citation	Description	Baseline penalty	Adjustment multiplier (year)	Amount after adjustment multiplier is applied to aseline penalty	Current penalty	Subject to cap?	Adjusted maximum
16 CFR 1.98(a) 15 U.S.C. 18a(g)(1).	Premerger filing notification violations.	$10,000	[8] 4.10774 (1976)	$41,077	$16,000	Yes	$40,000
16 CFR 1.98(b) 15 U.S.C. 21(*l*)	Violations of Clayton Act cease and desist orders.	5,000	[9] 8.08973 (1959)	40,449	8,500	Yes	21,250
16 CFR 1.98(c) 15 U.S.C. 45(*l*)	Violations of FTC Act cease and desist orders.	10,000	[10] 5.21575 (1973)	52,158	16,000	Yes	40,000
16 CFR 1.98(d) 15 U.S.C. 45(m)(1)(A).	Unfair or deceptive acts or practices.	10,000	[11] 4.33220 (1975)	43,322	16,000	Yes	40,000
16 CFR 1.98(e) 15 U.S.C. 45(m)(1)(B).	Unfair or deceptive acts or practices.	10,000	[12] 4.33220 (1975)	43,322	16,000	Yes	40,000
16 CFR 1.98(f) 15 U.S.C. 50	Failure to file required reports	100	[13] 23.54832 (1914)	2,355	210	Yes	525
1.98(g) 15 U.S.C. 65	Failure to file required statements	100	[14] 14.86488 (1918)	1,487	210	Yes	525
1.98(h) 15 U.S.C. 68d(b)	Failure to maintain required records.	100	[15] 16.98843 (1940)	1,699	210	Yes	525
1.98(i) 15 U.S.C. 69a(e)	Failure to maintain required records.	100	[16] 9.07779 (1951)	908	210	Yes	525
1.98(j) 15 U.S.C. 69f(d)(2)	Failure to maintain required records.	100	[17] 9.07779 (1951)	908	210	Yes	525
1.98(k) 42 U.S.C. 6303(a)	Knowing violations	100	[18] 4.33220 (1975)	433	210	No	433
1.98(*l*) 42 U.S.C. 6395(a)	Recycled oil labeling violations	5,000	[19] 4.33220 (1975)	21,661	8,500	Yes	21,250
1.98(*l*) 42 U.S.C. 6395(b)	Willful violations	10,000	[20] 4.33220 (1975)	43,322	16,000	Yes	40,000
1.98(m) 15 U.S.C. 1681s(a)(2)	Knowing violations	2,500	[21] 1.50245 (1996)	3,756	3,500	No	3,756
1.98(n) 21 U.S.C. 355 note	Non-compliance with filing requirements.	11,000	[22] 1.28561 (2003)	14,142	12,100	No	14,142
1.98(o) 42 U.S.C. 17304	Market manipulation or provision of false information to federal agencies.	1,000,000	[23] 1.13833 (2007)	1,138,330	1,100,000	No	1,138,330

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[6] 28 U.S.C. 2461 note (4)(b); Office of Management and Budget, M–16–06, Memorandum for the Heads of Executive Departments and Agencies, *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (Feb. 24, 2016), available at *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-06.pdf.* The OMB memorandum provides multipliers to adjust the penalty level based on the year the penalty was established or last adjusted pursuant to law.

[7] *Id.* note (4)(c).

[8] Public Law 94–435, 90 Stat. 1383 (1976).

[9] Public Law Public Law 86–107, 73 Stat. 243 (1959).

[10] Public Law Public Law 93–153, 87 Stat. 591 (1973).

[11] Public Law Public Law 93–637, 88 Stat. 2193 (1975).

[12] *Id.*

[13] Public Law 63–203, 38 Stat. 717 (1914).

[14] Public Law 65–126, 40 Stat. 517 (1918).

[15] Public Law 76–850, 54 Stat. 1128 (1940).

[16] Public Law 82–109, 65 Stat. 176 (1951).

[17] *Id.*

[18] Public Law 94–163, 89 Stat. 871 (1975).

[19] *Id.*

[20] *Id.*

[21] Public Law 104–208, 110 Stat. 3009 (1996).

[22] Public Law 108–173, 117 Stat. 2066 (2003).

[23] Public Law 110–140, 121 Stat. 1724 (2007).

Effective Dates of New Penalties

The Adjustment Improvements Act applies to civil penalties assessed after the effective date of the applicable adjustment, including civil penalties whose associated violation predated the effective date.[24] The Act does not retrospectively change previously assessed or enforced civil penalties.

Procedural Requirements

The Commission finds good cause for adopting this interim final rule without advance public notice or an opportunity for prior public comment. Advance opportunity for notice and comment are not required "when the agency for good cause finds (and incorporates the findings and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(3)(B). The Adjustment Improvements Act directs agencies to promulgate the required inflation adjustments through an interim final rulemaking by no later than July 1, 2016. Pursuant to this Congressional mandate, and because the Commission must adjust its civil penalties according to the statutory formula identified in the Adjustment Improvements Act, the Commission finds that good cause exists to forego prior public notice and comment under the APA. *Id.* These adjustments are mandated by statute and do not involve the exercise of Commission discretion or any policy judgments. Accordingly, the Commission finds that prior public notice and comment is unnecessary. For this reason, the requirements of the Regulatory Flexibility Act ("RFA") also do not apply.[25] Finally, this rule does not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995 as amended. 44 U.S.C. 3501 *et seq.*

List of Subjects for 16 CFR Part 1

Administrative practice and procedure, Penalties, Trade practices.

Text of Amendments

For the reasons set forth in the preamble, the Federal Trade Commission amends Title 16, chapter I, subchapter A, of the Code of Federal Regulations, as follows:

PART 1—GENERAL PROCEDURES

■ 1. Revise subpart L to read as follows:

Subpart L—Civil Penalty Adjustments Under the Federal Civil Penalties Inflation Adjustment Act of 1990, as Amended

Authority: 28 U.S.C. 2461 note.

§ 1.98 Adjustment of civil monetary penalty amounts.

This section makes inflation adjustments in the dollar amounts of civil monetary penalties provided by law within the Commission's jurisdiction. The following maximum civil penalty amounts apply only to penalties assessed after August 1, 2016, including those penalties whose associated violation predated August 1, 2016.

(a) Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1)—$40,000;

(b) Section 11(*l*) of the Clayton Act, 15 U.S.C. 21(*l*)—$21,250;

(c) Section 5(*l*) of the FTC Act, 15 U.S.C. 45(*l*)—$40,000;

(d) Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. 45(m)(1)(A)—$40,000;

(e) Section 5(m)(1)(B) of the FTC Act, 15 U.S.C. 45(m)(1)(B)—$40,000;

(f) Section 10 of the FTC Act, 15 U.S.C. 50—$525;

(g) Section 5 of the Webb-Pomerene (Export Trade) Act, 15 U.S.C. 65—$525;

(h) Section 6(b) of the Wool Products Labeling Act, 15 U.SC. 68d(b)—$525;

(i) Section 3(e) of the Fur Products Labeling Act, 15 U.S.C. 69a(e)—$525;

(j) Section 8(d)(2) of the Fur Products Labeling Act, 15 U.S.C. 69f(d)(2)—$525;

(k) Section 333(a) of the Energy Policy and Conservation Act, 42 U.S.C. 6303(a)—$433;

(l) Sections 525(a) and (b) of the Energy Policy and Conservation Act, 42 U.S.C. 6395(a) and (b), respectively—$21,250 and $40,000, respectively;

(m) Section 621(a)(2) of the Fair Credit Reporting Act, 15 U.S.C. 1681s(a)(2)—$3,756;

(n) Section 1115(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108–173, 21 U.S.C. 355 note—$14,142;

(o) Section 814(a) of the Energy Independence and Security Act of 2007, 42 U.S.C. 17304—$1,138,330; and

(p) Civil monetary penalties authorized by reference to the Federal Trade Commission Act under any other provision of law within the jurisdiction of the Commission—refer to the amounts set forth in paragraphs (c), (d), (e) and (f) of this section, as applicable.

By direction of the Commission.

April Tabor,

Acting Secretary.

[FR Doc. 2016–15302 Filed 6–29–16; 8:45 am]

BILLING CODE 6750–01–P

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[24] Public Law 114–74, 701(b)(3) (amending section 6 of the FCPIAA).

[25] A regulatory flexibility analysis under the RFA is required only when an agency must publish a notice of proposed rulemaking for comment. *See* 5 U.S.C. 603.

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167A2100DD/AAKC001030/ A0A501010.999900 253G]

25 CFR Parts 140, 141, 211, 213, 225, 226, 227, 243, 249

RIN 1076–AF32

Civil Penalties Inflation Adjustments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Interim final rule.

SUMMARY: This rule adjusts the level of civil monetary penalties contained in Indian Affairs regulations with an initial "catch-up" adjustment under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on August 1, 2016. Comments will be accepted until August 29, 2016.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Search for Docket No. BIA–2016–0004 and follow the instructions for submitting comments.
- *Mail, Hand Delivery, or Courier:* Elizabeth Appel, Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Dept. of the Interior, 1849 C Street NW., Mail Stop 3642, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Director, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs; telephone (202) 273–4680, *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Description of Changes
III. Procedural Requirements
  A. Regulatory Planning and Review (E.O. 12866)
  B. Regulatory Flexibility Act
  C. Small Business Regulatory Enforcement Fairness Act
  D. Unfunded Mandates Reform Act
  E. Takings (E.O. 12630)
  F. Federalism (E.O. 13132)
  G. Civil Justice Reform (E.O. 12988)
  H. Consultation with Indian Tribes (E.O. 13175)

I. Paperwork Reduction Act
J. National Environmental Policy Act
K. Effects on the Energy Supply (E.O. 13211)
L. Clarity of this Regulation
M. Administrative Procedure Act

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74). The Act requires Federal agencies to adjust the level of civil monetary penalties with an initial catch-up adjustment through rulemaking and then make subsequent annual adjustments for inflation. This rule adjusts the level of civil monetary penalties within those parts of Title 25 of the Code of Federal Regulations that fall under Chapter I, the Bureau of Indian Affairs. This rule does not affect criminal penalties, such as those at 25 CFR 273.15. This rule does not affect Chapter V, Bureau of Indian Affairs, and Indian Health Service or Chapter VI, Office of the Assistant Secretary, Indian Affairs, because those chapters contain no civil monetary penalties. This rule does not affect Chapter III, National Indian Gaming Commission, or Chapter IV, Office of Navajo and Hopi Indian Relocation, because those respective offices will determine whether it is necessary to issue separate rulemakings.

The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes. This rule adjusts the following civil monetary penalties, as calculated in accordance with the procedures described in Section II, Calculation of Adjustment:

CFR Citation	Description of penalty	Current penalty	Catchup adjustment multiplier	Adjusted penalty
25 CFR 140.3	Penalty for trading in Indian country without a license	$500	2.50000	$1,250
25 CFR 141.50	Penalty for trading on Navajo, Hopi or Zuni reservations without a license.	500	2.50000	1,250
25 CFR 211.55	Penalty for violation of leases of Tribal land for mineral development, violation of part 211, or failure to comply with a notice of noncompliance or cessation order.	1,000	1.50245	1,502
25 CFR 213.37	Penalty for failure of lessee to comply with lease of restricted lands of members of the Five Civilized Tribes in Oklahoma for mining, operating regulations at part 213, or orders.	500	2.50000	1,250
25 CFR 225.37	Penalty for violation of minerals agreement, regulations at part 225, other applicable laws or regulations, or failure to comply with a notice of noncompliance or cessation order.	1,000	1.59089	1,591
25 CFR 226.42	Penalty for violation of lease of Osage reservation lands for oil and gas mining or regulations at part 226, or noncompliance with the Superintendent's order.	500	1.78156	891
25 CFR 226.43(a)	Penalty per day for failure to obtain permission to start operations ..	50	1.78156	89
25 CFR 226.43(b)	Penalty per day for failure to file records	50	1.78156	89
25 CFR 226.43(c)	Penalty for each well and tank battery for failure to mark wells and tank batteries.	50	1.78156	89
25 CFR 226.43(d)	Penalty each day after operations are commenced for failure to construct and maintain pits.	50	1.78156	89
25 CFR 226.43(e)	Penalty for failure to comply with requirements regarding valve or other approved controlling device.	100	1.78156	178
25 CFR 226.43(f)	Penalty for failure to notify Superintendent before drilling, redrilling, deepening, plugging, or abandoning any well.	200	1.78156	356
25 CFR 226.43(g)	Penalty per day for failure to properly care for and dispose of deleterious fluids.	500	1.78156	891
25 CFR 226.43(h)	Penalty per day for failure to file plugging and other required reports.	50	1.78156	89
25 CFR 227.24	Penalty for failure of lessee of certain lands in Wind River Indian Reservation, Wyoming, for oil and gas mining to comply with lease provisions, operating regulations, regulations at part 227, or orders.	500	2.50000	1,250
25 CFR 243.8	Penalty for non-Native transferees of live Alaskan reindeer who violates part 243, takes reindeer without a permit, or fails to abide by permit terms..	5,000	1.17858	5,893
25 CFR 249.6(b)	Penalty for fishing in violation of regulations at part 249 (Off-Reservation Treaty Fishing)..	500	2.50000	1,250

II. Calculation of Adjustment

The OMB issued guidance on calculating the catch-up adjustment. *See* February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.* Under this guidance the Department of the Interior (Department) has identified applicable civil monetary penalties and calculated the catch-up adjustment. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. The calculated catch-up adjustment is based on the percent change between the Consumer Price Index for all Urban Consumers (CPIO–U) for the month of October in the year of the previous adjustment (or in the year of establishment, if no adjustment has been made) and the October 2015 CPI–U.

III. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). The Federal Civil Penalties Adjustment Act of 2015 requires agencies to adjust civil penalties with an initial catch-up adjustment through an interim final rule. An interim final rule does not include first publishing a proposed rule. Thus, the RFA does not apply to this final rule.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more;

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions;

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under E.O. 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in E.O. 13175 and have determined that is has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. (For further information, see 43 CFR 46.210(i).) We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

L. Clarity of This Regulation

We are required by E.O. 12866 (section 1(b)(12)), and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you think lists or tables would be useful, etc.

M. Administrative Procedure Act

The Act requires agencies to publish interim final rules by July 1, 2016, with an effective date for the adjusted penalties no later than August 1, 2016. To comply with the Act, we are issuing these regulations as an interim final rule and are requesting comments post-promulgation. Section 553(b) of the Administrative Procedure Act (APA) provides that, when an agency for good cause finds that "notice and public procedure . . . are impracticable, unnecessary, or contrary to the public interest," the agency may issue a rule without providing notice and an opportunity for prior public comment. The Bureau of Indian Affairs (BIA) finds that there is good cause to promulgate this rule without first providing for public comment. It would not be possible to meet the deadlines imposed by the Act if we were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and publish a final rule. Also, BIA is promulgating this final rule to implement the statutory directive in the Act, which requires agencies to publish an interim final rule and to update the civil penalty amounts by applying the specified formula. BIA has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for pre-promulgation public comment on this rule. Thus, pre-promulgation notice and public comment is impracticable and unnecessary.

List of Subjects

25 CFR Part 140

Business and industry, Indians, Penalties.

25 CFR Part 141

Business and industry, Credit, Indians—business and finance, Penalties.

25 CFR Part 211

Geothermal energy, Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR Part 213

Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR Part 225

Geothermal energy, Indians—lands, Mineral resources, Mines, Oil and gas exploration, Penalties, Reporting and recordkeeping requirements, Surety bonds.

25 CFR Part 226

Indians—lands.

25 CFR Part 227

Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR Part 243

Indians, Livestock.

25 CFR Part 249

Fishing, Indians.

For the reasons given in the preamble, the Department of the Interior amends Chapter I of title 25 Code of Federal Regulations as follows.

PART 140—LICENSED INDIAN TRADERS

■ 1. The authority citation for part 140 is revised to read as follows:

Authority: Sec. 5, 19 Stat. 200, sec. 1, 31 Stat. 1066 as amended; 25 U.S.C. 261, 262; 94 Stat. 544, 18 U.S.C. 437; 25 U.S.C. 2 and 9; 5 U.S.C. 301; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 140.3 [Amended]

■ 2. In § 140.3, remove "$500" and add in its place "$1,250".

PART 141—BUSINESS PRACTICES ON THE NAVAJO, HOPI AND ZUNI RESERVATIONS

■ 3. The authority citation for part 141 is revised to read as follows:

Authority: 5 U.S.C. 301; 25 U.S.C. 2 and 9; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 141.50 [Amended]

■ 4. In § 141.50, remove "five hundred dollars ($500)" and add in its place "$1,250".

PART 211—LEASING OF TRIBAL LANDS FOR MINERAL DEVELOPMENT

■ 5. The authority citation for part 211 is revised to read as follows:

Authority: Sec. 4, Act of May 11, 1938 (52 Stat. 347); Act of August 1, 1956 (70 Stat. 744); 25 U.S.C. 396a–g; 25 U.S.C. 2 and 9; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 211.55 [Amended]

■ 6. In § 211.55(a), remove "$1,000" and add in its place "$1,502".

PART 213—LEASING OF RESTRICTED LANDS FOR MEMBERS OF FIVE CIVILIZED TRIBES, OKLAHOMA, FOR MINING

■ 7. The authority citation for part 213 is revised to read as follows:

Authority: Sec. 2, 35 Stat. 312; sec. 18, 41 Stat. 426; sec. 1, 45 Stat. 495; sec. 1, 47 Stat. 777; 25 U.S.C. 356; and Sec. 701, Pub. L. 114–74, 129 Stat. 599. Interpret or apply secs. 3, 11, 35 Stat. 313, 316; sec. 8, 47 Stat. 779, unless otherwise noted.

§ 213.37 [Amended]

■ 8. In § 213.37, remove "$500" and add in its place "$1,250".

PART 225—OIL AND GAS, GEOTHERMAL AND SOLID MINERALS AGREEMENTS

■ 9. The authority citation for part 225 is revised to read as follows:

Authority: 25 U.S.C. 2, 9, and 2101–2108; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

§ 225.37 [Amended]

■ 10. In § 225.37(a), remove "$1,000" and add in its place "$1,591".

PART 226—LEASING OF OSAGE RESERVATION LANDS FOR OIL AND GAS MINING

■ 9. The authority citation for part 226 is revised to read as follows:

Authority: Sec. 3, 34 Stat. 543; secs. 1, 2, 45 Stat. 1478; sec. 3, 52 Stat. 1034, 1035; sec. 2(a), 92 Stat. 1660; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

§ 226.42 [Amended]

■ 10. In § 226.42, remove "$500" and add in its place "$891".

§ 226.43 [Amended]

■ 11. In § 226.43:

■ a. Remove "$50" each time it appears and add in each place "$89" wherever it appears in this section.
■ b. In paragraph (e), remove "$100" and add in its place "$178".
■ c. In paragraph (f), remove "$200" and add in its place "$356".
■ d. In paragraph (g), remove "$500" and add in its place "$891".

PART 227—LEASING OF CERTAIN LANDS IN WIND RIVER INDIAN RESERVATION, WYOMING, FOR OIL AND GAS MINING

■ 12. The authority citation for part 227 is revised to read as follows:

Authority: Sec. 1, 39 Stat. 519; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 227.24 [Amended]

■ 13. In § 227.24, remove "$500" and add in its place "$1,250".

PART 243—REINDEER IN ALASKA

■ 14. The authority citation for part 243 is revised to read as follows:

Authority: Sec. 12, 50 Stat. 902; 25 U.S.C. 500K; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

§ 243.8 [Amended]

■ 15. In § 243.8(a), remove "$5000.00" and add in its place "$5,893".

PART 249—OFF-RESERVATION TREATY FISHING

■ 16. The authority citation for part 249 is revised to read as follows:

Authority: 25 U.S.C. 2, and 9; 5 U.S.C. 301; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 249.6 [Amended]

■ 17. In § 249.6(b), remove "$500" and add in its place "$1,250".

Dated: June 24, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–15534 Filed 6–29–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9773]

RIN 1545–BM70

Country-by-Country Reporting

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that require annual country-by-country reporting by certain United States persons that are the ultimate parent entity of a multinational enterprise group. The final regulations affect United States persons that are the ultimate parent entity of a multinational enterprise group that has annual revenue for the preceding annual accounting period of $850,000,000 or more.

DATES: *Effective Date:* These regulations are effective June 30, 2016.

Applicability Date: For dates of applicability, *see* § 1.6038–4(k).

FOR FURTHER INFORMATION CONTACT: Melinda E. Harvey, (202) 317–6934 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The IRS intends that the information collection requirements in these regulations will be satisfied by submitting a new reporting form, Form 8975, *Country-by-Country Report,* with an income tax return. For purposes of the Paperwork Reduction Act, the reporting burden associated with the collection of information in these regulations will be reflected in the OMB Form 83–1, *Paperwork Reduction Act Submission,* associated with Form 8975.

Background

This document contains amendments to 26 CFR part 1. On December 23, 2015, a notice of proposed rulemaking (REG–109822–15) relating to the furnishing of country-by-country (CbC) reports by certain United States persons (U.S. persons) was published in the **Federal Register** (80 FR 79795). A public hearing was requested and was held on May 13, 2016. Comments responding to the notice of proposed rulemaking were received. After consideration of the comments, the proposed regulations are adopted as amended by this Treasury decision. The public comments and revisions are discussed below.

Summary of Comments and Explanation of Revisions

1. United States Participation in CbC Reporting

Multiple comments expressed support for the implementation of CbC reporting in the United States. However, one comment recommended that the Treasury Department and the IRS decline to implement CbC reporting because, according to the comment, U.S. multinational enterprise (MNE) groups' direct costs of compliance will exceed the United States Treasury's revenue gains, and there will be high, unanticipated costs from inadvertent disclosures of sensitive information. This recommendation is not adopted. U.S. MNE groups will be subject to CbC filing obligations in other countries in which they do business if the United States does not implement CbC reporting. Thus, a decision by the Treasury Department and the IRS not to implement CbC reporting will result in no compliance cost savings to U.S. MNE groups. In fact, failure to adopt CbC reporting requirements in the United States may increase compliance costs because U.S. MNE groups may be subject to CbC filing obligations in multiple foreign tax jurisdictions. U.S. MNE groups might also be subject to varying CbC filing rules and requirements in different foreign tax jurisdictions, such as requirements to prepare the CbC report using the local currency or language.

In addition, CbC reports filed with the IRS and exchanged pursuant to a competent authority arrangement benefit from the confidentiality requirements, data safeguards, and appropriate use restrictions in the competent authority arrangement. If a foreign tax jurisdiction fails to meet the confidentiality requirements, data safeguards, and appropriate use restrictions set forth in the competent authority arrangement, the United States will pause exchanges of all reports with that tax jurisdiction. Moreover, if such tax jurisdiction has adopted CbC reporting rules that are consistent with the 2015 Final Report for Action 13 (Transfer Pricing Documentation and Country-by-Country Reporting) of the Organisation for Economic Co-operation and Development (OECD) and Group of Twenty (G20) Base Erosion and Profit Shifting (BEPS) Project (Final BEPS Report), the tax jurisdiction will not be able to require any constituent entity of the U.S. MNE group in the tax jurisdiction to file a CbC report. The ability of the United States to pause exchange creates an additional incentive for foreign tax jurisdictions to uphold the confidentiality requirements, data safeguards, and appropriate use restrictions in the competent authority arrangement.

2. Form 8975, Country-by-Country Report

At the time of publication of the proposed regulations, the country-by-country reporting form described in the proposed regulations had not been officially numbered and was referred to in the proposed regulations as Form XXXX, *Country-by-Country Report.* The country-by-country reporting form remains under development but has been officially numbered. The final regulations amend the proposed regulations to reflect the official number of the form, Form 8975, *Country-by-Country Report,* (Form 8975 or CbCR).

3. Constituent Entities and Persons Required To File Form 8975

In the preamble to the proposed regulations, the Treasury Department and the IRS requested comments regarding whether additional guidance was needed for determining which U.S. persons must file Form 8975 or which entities are considered constituent entities of the filer. Specifically, the Treasury Department and the IRS requested comments on whether additional guidance on the definition of a U.S. MNE group was necessary to address situations where U.S. generally accepted accounting principles (GAAP) or U.S. securities regulations permit or require consolidated financial accounting for reasons other than majority ownership, as well as situations, if any, where U.S. GAAP or U.S. securities regulations permit separate financial accounting with respect to majority-owned enterprises.

A. Variable Interest Entities

Multiple comments addressed the inclusion of variable interest entities (VIEs) as constituent entities that are part of the U.S. MNE group. In general, a VIE may be consolidated with another entity for financial accounting purposes, even though that other entity may not control the VIE within the meaning of section 6038(e). Some comments recommended against expanding the definition of a U.S. MNE group to include VIEs and further recommended that, if those entities are nonetheless included, an exception should apply in cases in which the U.S. MNE group is unable to obtain the necessary information from a VIE. Other comments expressed concern that entities like VIEs would be part of the MNE group for purposes of foreign law relating to CbC reporting and, for consistency with such law, recommended that U.S. MNE groups be permitted to include such entities. Still other comments recommended that the definition of constituent entity should not be limited to majority-owned entities and should be expanded to include entities in which the ultimate parent entity owns, directly or indirectly, a 20-percent or greater equity interest.

The final regulations do not modify the definition of constituent entity in the proposed regulations. Because the final regulations are promulgated under the authority of section 6038, the definition of control in section 6038(e) limits the foreign business entities for which U.S. persons can be required to furnish information. Thus, the information described in § 1.6038–4(d)(1) and (2) is not required for foreign corporations or foreign partnerships for which the ultimate parent entity is not required to furnish information under section 6038(a) (determined without regard to §§ 1.6038–2(j) and 1.6038–3(c)) or any permanent establishment of such foreign corporation or foreign partnership.

B. Permanent Establishments

Under proposed § 1.6038–4(b)(2), a business entity includes a business establishment in a jurisdiction that is treated as a permanent establishment under an income tax convention to which that jurisdiction is a party, or that would be treated as a permanent establishment under the OECD Model Tax Convention on Income and on Capital 2014 (OECD Model Tax Convention), and that prepares financial statements separate from those of its owner for financial reporting, regulatory, tax reporting, or internal management control purposes. One comment recommended that the reference to the OECD Model Tax Convention be revised to account for changes to the definition of permanent establishment that will be incorporated into the OECD Model Tax Convention as a result of work under Action 7 (Preventing the Artificial Avoidance of Permanent Establishment Status) of the BEPS Project.

Upon further consideration, and taking into account the comment received, the Treasury Department and the IRS have determined it would be more appropriate for the final regulations to modify the proposed regulations' reference to a permanent establishment in the definition of business entity for greater clarity and consistency with the intended meaning of the Final BEPS Report. Accordingly, the final regulations provide that the term permanent establishment includes (i) a branch or business establishment of a constituent entity in a tax jurisdiction that is treated as a permanent establishment under an income tax convention to which that tax jurisdiction is a party, (ii) a branch or business establishment of a constituent entity that is liable to tax in the tax jurisdiction in which it is located pursuant to the domestic law of such tax jurisdiction, or (iii) a branch or business establishment of a constituent entity that is treated in the same manner for tax purposes as an entity separate from its owner by the owner's tax jurisdiction of residence. This approach is more consistent with the Final BEPS Report and generally would avoid the need for a U.S. MNE group that has already determined under applicable law whether it has a permanent establishment or a taxable business presence in a particular jurisdiction to make another determination under the OECD Model Tax Convention solely for purposes of completing the CbCR.

C. Grantor Trusts and Decedents' Estates

Proposed § 1.6038–4(b)(2) defines a business entity as a person, as defined in section 7701(a)(1), that is not an individual. Under this definition, a grantor trust with an individual owner or owners would be a business entity that could be subject to CbC reporting, notwithstanding that the individual owner or owners are generally treated as the owner of the grantor trust's property for federal income tax purposes and would not be subject to CbC reporting if they owned the property directly. Similarly, under the proposed regulations, a decedent's estate would be a business entity that could be subject to CbC reporting, notwithstanding that during the decedent's lifetime, he or she was an individual exempt from CbC reporting. Additionally, under the proposed regulations, an individual's bankruptcy estate would be a business entity that could be subject to CbC reporting, notwithstanding that before entering bankruptcy, the individual debtor would not be subject to CbC reporting. In light of the nature of grantor trusts, decedents' estates, and individuals' bankruptcy estates and their close connection to individual grantors, decedents, and individual debtors, the Treasury Department and the IRS have determined that it is not appropriate to include grantor trusts with only individual owners, decedents' estates, and individuals' bankruptcy estates in the definition of business entity. Accordingly, the final regulations exclude decedents' estates, individuals' bankruptcy estates, and grantor trusts within the meaning of section 671, all the owners of which are individuals, from the definition of business entity.

D. Deemed Domestic Corporations

The proposed regulations define a U.S. business entity as a business entity that is organized, or has its tax jurisdiction of residence, in the United States. One comment requested that the final regulations clarify whether companies that elect to be treated as domestic corporations under section 953(d) will be treated as U.S. business entities resident in the United States. In response to this comment, the final regulations expressly provide that foreign insurance companies that elect to be treated as domestic corporations under section 953(d) are U.S. business entities that have their tax jurisdiction of residence in the United States.

4. National Security Exception

The preamble to the proposed regulations requested comments on the need for a national security exception for reporting CbC information and on procedures for a taxpayer to demonstrate that such an exception is warranted. Multiple comments stated that the information provided on a CbCR does not present a national security concern. Other comments recommended that the final regulations include a national security exception but did not recommend an appropriate scope of the exception or procedures to demonstrate that an exception is warranted in a particular case. One comment recommended that no information should appear on a CbCR with respect to activities performed by a constituent entity of a U.S. MNE group under a U.S. government contract with certain agencies. Other comments recommended a bright-line test whereby U.S. MNE groups that conduct a majority of their business with the U.S. Department of Defense or U.S. government intelligence or security agencies could claim an automatic exception from reporting any information other than identifying information, such as company names, jurisdictions of incorporation, tax identification numbers, and addresses. These comments also recommended that U.S. MNE groups that conduct a significant amount (for example, more than 25 percent) of their business with the U.S. Department of Defense or U.S. government intelligence or security agencies should be allowed, with the approval of the IRS, to claim a similar exemption from reporting.

The Treasury Department and the IRS have consulted with the Department of Defense regarding the information collected on the CbCR. The Department of Defense concluded that such information reporting generally does not pose a national security concern. Accordingly, the final regulations do not provide a general exception for information that may relate to national security. Nonetheless, the Department of Defense continues to consider the national security implications of the CbCR in particular fact patterns, and future guidance may be issued to provide procedures for taxpayers to consult with the Department of Defense regarding the appropriate presentation of CbC information in such fact patterns.

5. Partnerships and Stateless Entities

A business entity that is treated as a partnership in the tax jurisdiction in which it is organized and that does not own or create a permanent establishment in that or another tax jurisdiction generally will have no tax jurisdiction of residence under the definition in proposed § 1.6038–4(b)(6) other than for purposes of determining the ultimate parent entity of a U.S. MNE group. Under the proposed regulations, tax jurisdiction information with respect to constituent entities that do not have a tax jurisdiction of residence, or “stateless entities,” would be aggregated and reported in a separate row of the CbCR. The preamble to the proposed regulations indicates that partners of a partnership that is a stateless entity would report their respective shares of the partnership's items in their respective tax jurisdiction(s) of residence.

A comment requested clarification as to whether the partnership or its partners, or both, should report the partnership's CbC information. In response, the final regulations provide that the tax jurisdiction of residence information with respect to stateless entities is provided on an aggregate basis for all stateless entities in a U.S. MNE group and that each stateless entity-owner's share of the revenue and profit of its stateless entity is also included in the information for the tax jurisdiction of residence of the stateless entity-owner. This rule applies irrespective of whether the stateless entity-owner is liable to tax on its share of the stateless entity's income in the owner's tax jurisdiction of residence. In other words, the stateless entity-owner reports its share of the stateless entity's revenues and profits in the owner's tax jurisdiction of residence even if that jurisdiction treats the stateless entity as a separate entity for tax purposes. In the case in which a partnership creates a permanent establishment for itself or its partners, the CbC information with respect to the permanent establishment is not reported as stateless, but instead is reported as part of the information on the CbCR for the permanent establishment's tax jurisdiction of residence.

A comment requested clarification regarding whether distributions from partnerships and other fiscally transparent entities should be excluded from owners'/partners' reported revenue. In response, the final regulations clarify that distributions from a partnership to a partner are not included in the partner's revenue. Additionally, the final regulations provide that remittances from a permanent establishment to its constituent entity-owner are not included in the constituent entity-owner's revenue.

6. Clarification of Terms

The preamble to the proposed regulations requested comments on the manner in which the proposed regulations require the reporting of information on taxes paid or accrued by U.S. MNE groups and their constituent entities on taxable income earned in the relevant accounting period. One comment requested that “total accrued tax expense” in proposed § 1.6038–4(d)(2)(v) be revised to read “accrued current tax expense” in order to reflect only operations in the current year and not deferred taxes or provisions for uncertain tax liabilities. The proposed regulations clearly state that the relevant taxes to be reported relate only to the annual accounting period for which the CbCR is provided and exclude deferred taxes and provisions for uncertain tax liabilities. Therefore, the comment is not adopted.

The preamble to the proposed regulations also requested comments on whether the descriptions of any of the other items in § 1.6038–4(d)(2)(i) through (ix) regarding tax jurisdiction of residence information should be further refined or whether additional guidance is needed with respect to how to determine any of these items. One comment requested that the definition for tangible assets be revised to clarify that intangibles and financial assets are excluded consistent with the Final BEPS Report. In response, the final regulations expressly provide that tangible assets do not include intangibles or financial assets.

A comment noted that the term revenue excludes dividends from other constituent entities and recommended that this exclusion be extended to all forms of imputed earnings or deemed dividends. The Treasury Department and the IRS agree that imputed earnings and deemed dividends that are taken into account solely for tax purposes should be treated the same as dividends for purposes of the CbCR. Accordingly, the final regulations incorporate this recommendation.

Multiple comments recommended that the wording “total income tax paid on a cash basis to all jurisdictions” in proposed § 1.6038–4(d)(2)(iv) should be modified to read “total income tax paid on a cash basis to each tax jurisdiction” to avoid misinterpretation of the “all tax jurisdictions” language to require taxes paid by entities that are tax residents of different tax jurisdictions to be aggregated rather than reported on a country-by-country basis as intended. The Treasury Department and the IRS interpret the language of the proposed regulation to require the total income tax paid on a cash basis to any tax jurisdiction by constituent entities that have a tax residence in a particular tax jurisdiction to be reported on an aggregated basis for that particular tax jurisdiction of residence but not the aggregation of taxes paid by constituent entities that have different tax residences. For instance, if a constituent entity pays income tax in its tax jurisdiction of residence on its earnings from operations in that country and is subject to withholding taxes on royalties received from licensees in another country, taxes paid with respect to the income and the taxes withheld with respect to the royalties should be reflected on an aggregated basis on the CbCR in the row for the constituent entity's tax jurisdiction of residence. The Treasury Department and the IRS are concerned that the alternative language proposed in the comments could be misinterpreted to require amounts paid to different tax jurisdictions by constituent entities resident in a single tax jurisdiction to be reported on a disaggregated basis. Accordingly, this comment is not adopted.

Multiple comments also recommended the inclusion of two additional items, deferred taxes and provisions for uncertain tax positions, in the information required to be reported on a tax jurisdiction-by-tax jurisdiction basis. This recommendation has not been adopted in the final regulations because it would impose an additional reporting burden beyond the information described in the Final BEPS Report.

Multiple comments recommended that the final regulations clarify that the information listed in proposed § 1.6038–4(d)(2)(i) through (ix) is reported in the aggregate for all constituent entities resident in each separate tax jurisdiction. Although the language in the proposed regulations does indicate that the information is to be provided with respect to each tax jurisdiction in which one or more constituent entities of the U.S. MNE group are resident and in the form and manner that Form 8975 prescribes, the final regulations provide additional language to clarify that the information is to be presented for each tax jurisdiction as an aggregate of the information for all constituent entities resident in that tax jurisdiction. Multiple comments requested that the final regulations clarify whether the information must be provided for only the constituent entities in each tax jurisdiction or whether the information must also be provided for U.S. MNE group members that are not constituent entities, for instance VIEs. The Treasury Department and the IRS have determined that additional language is unnecessary because § 1.6038–4(d)(1) of the proposed regulations expressly requires reporting of information only with respect to constituent entities of the U.S. MNE group.

The final regulations provide that, for a constituent entity that is an organization exempt from taxation under section 501(a) because it is an organization described in section 501(c), 501(d), or 401(a), a state college or university described in section 511(a)(2)(B), a plan described in section 403(b) or 457(b), an individual retirement plan or annuity as defined in section 7701(a)(37), a qualified tuition program described in section 529, a qualified ABLE program described in section 529A, or a Coverdell education savings account described in section 530, the term revenue includes only revenue that is included in unrelated business taxable income as defined in section 512.

7. Other Form or Information Modifications

Multiple comments recommended that additional information be included on the CbCR, such as identification of constituent entities as "pass-through" and a legal entity identifier for each constituent entity using a standard international system for identifying individual business entities. The final regulations do not adopt these recommendations because they would impose an additional reporting burden beyond the information described in the Final BEPS Report.

8. Voluntary Filing Before the Applicability Date

Other countries have adopted CbC reporting requirements for annual accounting periods beginning on or after January 1, 2016, that would require reporting of CbC information by constituent entities of MNE groups with an ultimate parent entity resident in a tax jurisdiction that does not have a CbC reporting requirement for the same annual accounting period. The proposed regulations generally require U.S. MNE groups to file a CbCR for taxable years beginning on or after the date the final regulations are published. Consequently, U.S. MNE groups that use a calendar year as their taxable year generally will not be required to file a CbCR for their taxable year beginning January 1, 2016, and constituent entities of such U.S. MNE groups may be subject to CbC reporting requirements in foreign jurisdictions. Comments expressed concern about this possibility and recommended various approaches for dealing with this issue. Most comments requested that the IRS accept and exchange CbCRs voluntarily filed for taxable years beginning on or after January 1, 2016.

Consistent with the proposed regulations, the final regulations are not applicable for taxable years of ultimate parent entities beginning before June 30, 2016, the date of publication of the final regulations in the **Federal Register**. Specifically, the final regulations apply to reporting periods of ultimate parent entities of U.S. MNE groups that begin on or after the first day of a taxable year of the ultimate parent entity that begins on or after June 30, 2016. The Treasury Department and the IRS intend to allow ultimate parent entities of U.S. MNE groups and U.S. business entities designated by a U.S. territory ultimate parent entity to file CbCRs for reporting periods that begin on or after January 1, 2016, but before the applicability date of the final regulations, under a procedure to be provided in separate, forthcoming guidance. The Treasury Department is working to ensure that foreign jurisdictions implementing CbC reporting requirements will not require constituent entities of U.S. MNE groups to file a CbC report with the foreign jurisdiction if the U.S. MNE group files a CbCR with the IRS pursuant to this procedure and the CbCR is exchanged with such foreign jurisdiction pursuant to a competent authority arrangement.

9. Time and Manner of Filing

The proposed regulations provide that the CbCR for a taxable year must be filed with the ultimate parent entity's income tax return for the taxable year on or before the due date, including extensions, for filing that person's income tax return. Multiple comments requested that taxpayers be permitted to file a CbCR up to one year from the end of the ultimate parent entity's taxable year or annual accounting period to facilitate the taxpayer's ability to use statutory accounts or tax records of constituent entities to complete the CbCR. After considering the flexibility allowed for sources of information for completing the CbCR, the IRS information technology resources necessary to facilitate a filing separate from the income tax return, and the IRS's concern that CbCRs be linked to an income tax return, the Treasury Department and the IRS have not adopted this recommendation. However, the final regulations do provide that Form 8975 may prescribe an alternative time and manner for filing.

10. Employees

The proposed regulations provide that the CbCR must reflect the number of employees for each tax jurisdiction of residence of the U.S. MNE group. The proposed regulations also provide that independent contractors participating in the ordinary course of business of a constituent entity may be included in the number of full-time equivalent employees. Multiple comments asked for further clarification with respect to the determination of the number of full-time equivalent employees and the treatment of independent contractors, including some recommending that independent contractors not be included as employees. The final regulations do not provide additional guidance with respect to the meaning of full-time equivalent employee or with respect to independent contractor situations and continue to allow for independent contractors that participate in the ordinary operating activities of a constituent entity to be included in the number of full-time equivalent employees. U.S. MNE groups may determine the number of employees of constituent entities on a full-time equivalent basis using any reasonable approach that is consistently applied. The Treasury Department and the IRS believe permitting this flexibility in determining the number of full-time equivalent employees of each constituent entity appropriately balances the burden of completing the CbCR with the anticipated benefits to tax administration and is consistent with the Final BEPS Report.

The proposed regulations specify that employees should be reflected on the CbCR in the tax jurisdictions in which the employees performed work for the U.S. MNE group. Comments indicated that this methodology is inconsistent with the Final BEPS Report, which provides that employees of a constituent entity should be reflected in the tax jurisdiction of residence of such constituent entity, and that determining the work location of employees would be burdensome for U.S. MNE groups and would present issues regarding certain employment situations with traveling employees. The comments recommended that the final regulations follow the approach of the Final BEPS Report. In response to these comments, the final regulations do not include the phrase "in the relevant tax jurisdiction" from proposed § 1.6038–4(d)(2)(viii). Accordingly, under the final regulations, employees of a constituent entity are reflected in the tax jurisdiction of residence of such constituent entity.

A comment requested clarification about the tax jurisdiction in which employees of partnerships should be reflected on the CbCR. As discussed in section 5 of this preamble, a partnership may be considered a stateless entity. If the partnership creates a permanent establishment for itself or its partners, then the permanent establishment itself may be a constituent entity of the U.S. MNE group. Employees of the permanent establishment-constituent entity should be reflected in the tax jurisdiction of residence of the permanent establishment. Any other employees of the partnership should be reported on the stateless jurisdiction row under the tax jurisdiction of residence information portion of the CbCR.

11. Source of Data and Reconciliation

The proposed regulations provide that the amounts furnished in the CbCR should be furnished for the annual accounting period with respect to which the ultimate parent entity prepares its applicable financial statements ending with or within the ultimate parent entity's taxable year, or, if the ultimate parent entity does not prepare applicable financial statements, then the information may be based on the applicable financial statements of constituent entities for their accounting period that ends with or within the ultimate parent entity's taxable year. Multiple comments expressed concern that the description of the period covered by the CbCR in the proposed regulations may limit the flexibility of U.S. MNE groups to choose to use consolidated financial statements or separate accounting, regulatory, or tax records prepared for the constituent entities. To mitigate this concern, the final regulations remove the restrictions imposed by the proposed regulations with respect to providing information for the applicable accounting period of the ultimate parent entity or for the applicable accounting period of each constituent entity. The final regulations provide that the reporting period covered by Form 8975 is the period of the ultimate parent entity's annual applicable financial statement that ends with or within the ultimate parent entity's taxable year, or, if the ultimate parent entity does not prepare an annual applicable financial statement, then the ultimate parent entity's taxable year. The final regulations do not limit the constituent entity information to applicable financial statements of the constituent entity but, rather, provide that the source of the tax jurisdiction of residence information on the CbCR must be based on applicable financial statements, books and records, regulatory financial statements, or records used for tax reporting or internal management control purposes for an annual period of each constituent entity ending with or within the reporting period.

The proposed regulations provide that the amounts provided in the CbCR should be based on applicable financial statements, books and records maintained with respect to the constituent entity, or records used for tax reporting purposes. The term "books and records" was intended to be broad enough to include all sources of information that the Final BEPS Report allows. In order to clarify this intent, the final regulations provide that the source of data may also include regulatory financial statements and records used for internal management control purposes.

The proposed regulations state that it is not necessary to have or maintain records that reconcile the amounts provided on the CbCR to the consolidated financial statements of the U.S. MNE group or to the tax returns filed in any particular tax jurisdiction or to make adjustments for differences in accounting principles applied from tax jurisdiction to tax jurisdiction. Multiple comments recommended that reconciliation to tax accounts be required and that ultimate parent entities maintain records of the reconciliation, while other comments supported the approach in the proposed regulations, which does not require reconciliation. The Treasury Department and the IRS considered these comments, and, consistent with the proposed regulations, the final regulations do not require the ultimate parent entity to create and maintain records to reconcile the information reported in the CbCR to consolidated financial statements or to tax returns. This approach provides flexibility for U.S. MNE groups to use the available data for each constituent entity without imposing the potential burden of a need to reconcile information on the CbCR with accounts that may not even be finalized when the CbCR is compiled, and it is consistent with the Final BEPS Report. The affirmative statement in the final regulations that an ultimate parent entity is not required to create and maintain information to support a reconciliation does not, however, affect the requirement to maintain records to support the information provided in the CbCR.

12. Expanding Scope and Surrogate Parent Entity Filing

The proposed regulations generally require a U.S. business entity that is an ultimate parent entity of a U.S. MNE group to file a CbCR with respect to business entities that are or would be consolidated with the ultimate parent entity. A CbCR is not required for an MNE group that does not have a U.S. business entity as its ultimate parent entity. Multiple comments requested that reporting be required for any U.S. entity that exercises the "mind and management function" of an MNE group, the foreign parent entity of which is tax resident in a jurisdiction that does not require a report similar to the CbCR, despite the fact that the foreign entities of such MNE group are not controlled foreign corporations. This recommendation, which is not adopted, is beyond the scope of the Final BEPS Report and could not be implemented under the authority provided in section 6038 to collect information on foreign business entities owned by U.S. persons.

One comment recommended that the final regulations allow a foreign-parented MNE group with a U.S. business entity to designate that U.S. business entity as a surrogate parent entity and allow that entity to file a CbCR with the IRS for purposes of satisfying the MNE group's country-by-country reporting obligations in other tax jurisdictions. In light of the IRS resources that would be required to adopt this recommendation, the final regulations do not permit surrogate parent entity filing in the United States by foreign corporations as a general matter. However, the final regulations provide that a U.S. territory ultimate parent entity may designate a U.S. business entity that it controls (as defined in section 6038(e)) to file on the U.S. territory ultimate parent entity's behalf the CbCR that the U.S. territory ultimate parent entity would be required to file if it were a U.S. business entity. A U.S. territory ultimate parent entity is a business entity organized in a U.S. territory or possession of the United States that controls (as defined in section 6038(e)) a U.S. business entity and that is not owned directly or indirectly by another business entity that consolidates the accounts of the U.S. territory ultimate parent entity with its accounts under GAAP in the other business entity's tax jurisdiction of residence, or would be so required if equity interests in the other business entity were traded on a public securities exchange in its tax jurisdiction of residence.

13. Tax Jurisdiction of Residence and Fiscal Autonomy

The proposed regulations provide rules for determining the tax jurisdiction of residence of a constituent entity. Under those rules, a business entity is considered a resident in a tax jurisdiction if, under the laws of that tax jurisdiction, the business entity is liable to tax therein based on place of management, place of organization, or another similar criterion. The proposed regulations further provide that "a business entity will not be considered a resident in a tax jurisdiction if such business entity is liable to tax in such tax jurisdiction solely with respect to income from sources in such tax jurisdiction, or capital situated in such tax jurisdiction." Multiple comments requested that the final regulations clarify that this language in the proposed regulations is not intended to exclude the possibility of a country with a purely territorial tax regime being a tax jurisdiction of residence. The Treasury Department and the IRS did not intend for the proposed regulations to be interpreted to treat all entities in tax jurisdictions with territorial tax regimes as stateless entities. The language in question was intended to indicate that a business entity will not have a tax jurisdiction of residence in a jurisdiction solely by reason of being liable to tax in the jurisdiction on fixed, determinable, annual or periodical income from sources or capital situated in the jurisdiction. For greater clarity, the final regulations provide that "[a] business entity will not be considered a resident in a tax jurisdiction if the business entity is only liable to tax in such tax jurisdiction by reason of a tax imposed by reference to gross amounts of income without any reduction for expenses, provided such tax applies only with respect to income from sources in such tax jurisdiction or capital situated in such tax jurisdiction."

The proposed regulations provide that a tax jurisdiction is a country or a jurisdiction that is not a country but that has fiscal autonomy. Multiple comments requested that the final regulations address the meaning of fiscal autonomy. In light of the need for consistency of CbC reporting requirements across tax jurisdictions, the Treasury Department and the IRS do not believe it would be helpful to provide a general definition of fiscal autonomy in the final regulations absent international consensus on the meaning of the term. However, the final regulations clarify that a U.S. territory or possession of the United States, defined as American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands, is considered to have fiscal autonomy for purposes of CbC reporting.

Under the proposed regulations, if a business entity is resident in more than one tax jurisdiction and there is no applicable income tax treaty, the business entity's tax jurisdiction of residence is the tax jurisdiction of the business entity's place of effective management determined in accordance with Article 4 of the OECD Model Tax Convention. One comment noted that the "effective place of management" test under the OECD Model Tax Convention can be uncertain and "subject to second guessing." The comment recommended that an alternative, bright-line tie-breaker rule be considered to address such situations. The determination of tax jurisdiction of residence in the proposed regulations is based on the Final BEPS Report, and the final regulations do not create a new tie-breaker rule but add that, in addition to the OECD Model Tax Convention, Form 8975 may provide guidance.

Although certain entities may not have a tax jurisdiction of residence, the Treasury Department and the IRS have determined that an entity regarded as a corporation should not be considered stateless merely because it is organized or managed in a jurisdiction that does not impose an income tax on corporations. Accordingly, the final regulations provide that in the case of a tax jurisdiction that does not impose an income tax on corporations, a corporation that is organized or managed in that tax jurisdiction will be treated as resident in that tax jurisdiction, unless such corporation is treated as resident in another tax jurisdiction under another provision of the final regulations.

14. Reporting Threshold

The revenue threshold at or above which a U.S. MNE group is required to file the CbCR (reporting threshold) is expressed in United States dollars (USD) in proposed § 1.6038–4(h). Foreign jurisdictions that are enacting CbC reporting requirements based on the Final BEPS Report may express the reporting threshold in a foreign currency. Multiple commenters expressed concern that U.S. MNE groups may be required to file a CbC report in a foreign country, even if the USD reporting threshold in § 1.6038–4(h) is not exceeded, because the U.S. MNE group's revenues exceed the local law reporting threshold as expressed in the foreign currency. The comments recommended various approaches to address the possibility of a reporting threshold in the final regulations that is inconsistent with local law reporting thresholds. The reporting threshold of $850,000,000 in the proposed regulation was determined by reference to the USD equivalent of €750,000,000 on January 1, 2015, as provided in the Final BEPS Report. The Treasury Department and the IRS anticipate that other countries will acknowledge that it would be inconsistent with the Final BEPS Report for a country to require local filing by a constituent entity of a U.S. MNE group that has revenue of less than $850,000,000.

Multiple comments requested that the reporting threshold be reduced to the USD equivalent of €40,000,000 in order to subject a greater number of U.S. MNE groups to CbC reporting requirements. Because the reporting threshold in the proposed regulations is based on the Final BEPS Report, it is consistent with the agreed international standard with respect to CbC reporting. The Treasury Department and IRS weighed the potential benefit of obtaining CbC information on a larger number of U.S.

MNE groups against the additional administrative burden that would be imposed on the IRS and the burden that would be imposed on U.S. MNE groups that would not otherwise be required to file the CbCR. Based on these considerations, the final regulations maintain the reporting threshold in the proposed regulations.

15. Confidentiality and Use of the CbCR

Multiple comments expressed concerns regarding the confidentiality of the CbCR. Some comments recommended public disclosure of CbCRs. These comments requested that the CbCR be treated as a Treasury report, referencing as an example the Treasury Department's Financial Crimes Enforcement Network Report of Foreign Bank and Financial Assets, rather than tax return information, so that the CbCR would not be subject to the confidentiality protections under section 6103. Other comments supported the decision to treat CbCR as return information.

The Treasury Department and the IRS have determined that the information provided on the CbCR is return information subject to the confidentiality protections of section 6103. This approach is consistent with the purpose of CbC reporting as well as the confidentiality standards reflected in the Final BEPS Report. CbC reporting was designed and established as part of an international effort to standardize transfer pricing documentation. This standardized documentation is intended to provide an efficient and effective means for tax administrations to conduct high-level transfer pricing risk assessment. Accordingly, the Treasury Department and the IRS are collecting the CbCR under the authority of sections 6001, 6011, 6012, 6031, and 6038 to assist in the better enforcement of income tax laws. The CbCR is a return, and the information furnished to the Treasury Department and the IRS on the CbCR is return information subject to the confidentiality protections provided under section 6103. In addition, the Final BEPS Report provides that tax administrations should take all reasonable steps to ensure that there is no public disclosure of confidential information in CbC reports and that they be used for tax risk assessment purposes.

The preamble of the proposed regulations indicates that the information reported on the CbCR will be used for high-level transfer pricing risk identification and assessment, and that transfer pricing adjustments will not be made solely on the basis of a CbCR, but that the CbCR may be the basis for further inquiries into transfer pricing practices or other tax matters which may lead to adjustments. Some comments supported the limitations on use of the CbCR information, while other comments expressed concern that a prohibition on disclosure of the CbCR for non-tax law purposes is too restrictive. Consistent with the proposed regulations, the final regulations do not contain specific limitations on the use of CbCR information. However, consistent with the Final BEPS Report, the Treasury Department and the IRS intend to limit the use of the CbCR information and intend to incorporate this limitation into the competent authority arrangements pursuant to which CbCRs are exchanged.

One comment recommended that CbCR information not be provided to state or local jurisdictions and that a statement to that effect be provided in the final regulations. Under section 6103(d), return information may be provided to state agencies, but only for the purposes of, and only to the extent necessary in, the administration of such state's tax laws. The Treasury Department and the IRS believe the circumstances under which this standard would be met for the CbCR are rare, but the final regulations do not preclude the disclosure of CbCRs to state agencies, subject to the restrictions of section 6103 that apply to other returns and return information.

16. Exchange of Information With Foreign Jurisdictions

The United States intends to enter into competent authority arrangements for the automatic exchange of CbCRs with jurisdictions with which the United States has an income tax treaty or tax information exchange agreement. Multiple comments expressed concern that review of the confidentiality safeguards and framework of the other jurisdictions would prevent the Treasury Department and IRS from concluding such arrangements on a timely basis. Comments also requested that the Treasury Department and IRS publish a list of jurisdictions with which the United States exchanges CbCRs. The Treasury Department is committed to entering into bilateral competent authority arrangements with respect to CbCRs in a timely manner, taking into consideration the need for appropriate review of systems and confidentiality safeguards in the other jurisdictions. The Treasury Department and the IRS anticipate that information about the existence of competent authority arrangements for CbCRs will be made publicly available, but the manner in which such information would be made publicly available has not yet been determined.

A comment recommended that the final regulations provide a mechanism for reporting suspected violations of the limitations on the use of information by foreign jurisdictions. While the final regulations do not provide procedures for reporting suspected violations, the Treasury Department and the IRS are aware of the concern and intend to establish a procedure to report suspected violations of confidentiality and other misuses of CbCR information.

A comment requested that information transmitted under the competent authority arrangements include the "Additional Information" table in the model CbC report template provided in the Final BEPS Report. It is expected that such information will be collected on Form 8975 and transmitted; however, there may be limits to the amount of information that can be transmitted in any field. Such constraints, if any, will be noted in the Instructions to Form 8975.

17. Penalties

One comment requested that penalties with respect to the CbCR be waived for reports filed for the 2016 tax year and that the Treasury Department should advocate that other countries also waive penalties for the 2016 tax year. The final regulations apply to reporting periods of ultimate parent entities that begin on or after the first day of a taxable year of the ultimate parent entity that begins on or after publication of the final regulations in the **Federal Register**. U.S. MNE groups whose ultimate parent entity's taxable year begins before the applicability date will not have a CbCR filing requirement for their tax year beginning in 2016. The final regulations do not provide a specific waiver of penalties for U.S. MNE groups whose ultimate parent entity's taxable year begins on or after the applicability date. The penalty rules under section 6038 generally apply, including reasonable cause relief for failure to file.

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It also has been determined that section 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6). Accordingly, a regulatory flexibility analysis is not required. This certification is based on the fact that these regulations will only affect U.S. corporations, partnerships, and business trusts that have foreign operations with respect to a taxable year when the combined annual revenue of the business entities owned by the U.S. person meets or exceeds $850,000,000 for the previous reporting period. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Melinda E. Harvey of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding the following entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

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Section 1.6038–4 also issued under 26 U.S.C. 6001, 6011, 6012, 6031, and 6038.

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■ **Par. 2.** Section 1.6038–4 is added to read as follows:

§ 1.6038–4 Information returns required of certain United States persons with respect to such person's U.S. multinational enterprise group.

(a) *Requirement of return.* Except as provided in paragraph (h) of this section, every ultimate parent entity of a U.S. multinational enterprise (MNE) group must make an annual return on Form 8975, *Country-by-Country Report,* setting forth the information described in paragraph (d) of this section, and any other information required by Form 8975, with respect to the reporting period described in paragraph (c) of this section.

(b) *Definitions*—(1) *Ultimate parent entity of a U.S. MNE group.* An ultimate parent entity of a U.S. MNE group is a U.S. business entity that:

(i) Owns directly or indirectly a sufficient interest in one or more other business entities, at least one of which is organized or tax resident in a tax jurisdiction other than the United States, such that the U.S. business entity is required to consolidate the accounts of the other business entities with its own accounts under U.S. generally accepted accounting principles, or would be so required if equity interests in the U.S. business entity were publicly traded on a U.S. securities exchange; and

(ii) Is not owned directly or indirectly by another business entity that consolidates the accounts of such U.S. business entity with its own accounts under generally accepted accounting principles in the other business entity's tax jurisdiction of residence, or would be so required if equity interests in the other business entity were traded on a public securities exchange in its tax jurisdiction of residence.

(2) *Business entity.* For purposes of this section, a business entity generally is any entity recognized for federal tax purposes that is not properly classified as a trust under § 301.7701–4 of this chapter. However, any grantor trust within the meaning of section 671, all or a portion of which is owned by a person other an individual, is a business entity for purposes of this section. Additionally, the term business entity includes any entity with a single owner that may be disregarded as an entity separate from its owner under § 301.7701–3 of this chapter and a permanent establishment, as defined in paragraph (b)(3) of this section, that prepares financial statements separate from those of its owner for financial reporting, regulatory, tax reporting, or internal management control purposes. A business entity does not include a decedent's estate or a bankruptcy estate described in section 1398.

(3) *Permanent establishment.* For purposes of this section, the term permanent establishment includes:

(i) A branch or business establishment of a constituent entity in a tax jurisdiction that is treated as a permanent establishment under an income tax convention to which that tax jurisdiction is a party;

(ii) A branch or business establishment of a constituent entity that is liable to tax in the tax jurisdiction in which it is located pursuant to the domestic law of such tax jurisdiction; or

(iii) A branch or business establishment of a constituent entity that is treated in the same manner for tax purposes as an entity separate from its owner by the owner's tax jurisdiction of residence.

(4) *U.S. business entity.* A U.S. business entity is a business entity that is organized or has its tax jurisdiction of residence in the United States. For purposes of this section, foreign insurance companies that elect to be treated as domestic corporations under section 953(d) are U.S. business entities that have their tax jurisdiction of residence in the United States.

(5) *U.S. MNE group.* A U.S. MNE group comprises the ultimate parent entity of a U.S. MNE group as defined in paragraph (b)(1) of this section and all of the business entities required to consolidate their accounts with the ultimate parent entity's accounts under U.S. generally accepted accounting principles, or that would be so required if equity interests in the ultimate parent entity were publicly traded on a U.S. securities exchange, regardless of whether any such business entities could be excluded from consolidation solely on size or materiality grounds.

(6) *Constituent entity.* With respect to a U.S. MNE group, a constituent entity is any separate business entity of such U.S. MNE group, except that the term constituent entity does not include a foreign corporation or foreign partnership for which the ultimate parent entity is not required to furnish information under section 6038(a) (determined without regard to §§ 1.6038–2(j) and 1.6038–3(c)) or any permanent establishment of such foreign corporation or foreign partnership.

(7) *Tax jurisdiction.* For purposes of this section, a tax jurisdiction is a country or a jurisdiction that is not a country but that has fiscal autonomy. For purposes of this section, a U.S. territory or possession of the United States is considered to have fiscal autonomy.

(8) *Tax jurisdiction of residence.* A business entity is considered a resident in a tax jurisdiction if, under the laws of that tax jurisdiction, the business entity is liable to tax therein based on place of management, place of organization, or another similar criterion. A business entity will not be considered a resident in a tax jurisdiction if the business entity is liable to tax in such tax jurisdiction only by reason of a tax imposed by reference to gross amounts of income without any reduction for expenses, provided such

tax applies only with respect to income from sources in such tax jurisdiction or capital situated in such tax jurisdiction. If a business entity is resident in more than one tax jurisdiction, then the applicable income tax convention rules, if any, should be applied to determine the business entity's tax jurisdiction of residence. If a business entity is resident in more than one tax jurisdiction and no applicable income tax convention exists between those tax jurisdictions, or if the applicable income tax convention provides that the determination of residence is based on a determination by the competent authorities of the relevant tax jurisdictions and no such determination has been made, the business entity's tax jurisdiction of residence is the tax jurisdiction of the business entity's place of effective management determined in accordance with Article 4 of the Organisation for Economic Co-operation and Development Model Tax Convention on Income and on Capital 2014, or as provided by Form 8975. A corporation that is organized or managed in a tax jurisdiction that does not impose an income tax on corporations will be treated as resident in that tax jurisdiction, unless such corporation is treated as resident in another tax jurisdiction under another provision of this section. The tax jurisdiction of residence of a permanent establishment is the jurisdiction in which the permanent establishment is located. If a business entity does not have a tax jurisdiction of residence, then solely for purposes of paragraph (b)(1) of this section, the tax jurisdiction of residence is the business entity's country of organization.

(9) *Applicable financial statements.* An applicable financial statement is a certified audited financial statement that is accompanied by a report of an independent certified public accountant or similarly qualified independent professional that is used for purposes of reporting to shareholders, partners, or similar persons; for purposes of reporting to creditors in connection with securing or maintaining financing; or for any other substantial non-tax purpose.

(10) *U.S. territory or possession of the United States.* The term U.S. territory or possession of the United States means American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands.

(11) *U.S. territory ultimate parent entity.* A U.S. territory ultimate parent entity is a business entity organized in a U.S. territory or possession of the United States that controls (as defined in section 6038(e)) a U.S. business entity and that is not owned directly or indirectly by another business entity that consolidates the accounts of the U.S. territory ultimate parent entity with its accounts under generally accepted accounting principles in the other business entity's tax jurisdiction of residence, or would be so required if equity interests in the other business entity were traded on a public securities exchange in its tax jurisdiction of residence.

(c) *Reporting period.* The reporting period covered by Form 8975 is the period of the ultimate parent entity's applicable financial statement prepared for the 12-month period (or a 52–53 week period described in section 441(f)) that ends with or within the ultimate parent entity's taxable year. If the ultimate parent entity does not prepare an annual applicable financial statement, then the reporting period covered by Form 8975 is the 12-month period (or a 52–53 week period described in section 441(f)) that ends on the last day of the ultimate parent entity's taxable year.

(d) *Contents of return*—(1) *Constituent entity information.* The return on Form 8975 must contain so much of the following information with respect to each constituent entity of the U.S. MNE group, and in such form or manner, as Form 8975 prescribes:

(i) The complete legal name of the constituent entity;

(ii) The tax jurisdiction, if any, in which the constituent entity is resident for tax purposes;

(iii) The tax jurisdiction in which the constituent entity is organized or incorporated (if different from the tax jurisdiction of residence);

(iv) The tax identification number, if any, used for the constituent entity by the tax administration of the constituent entity's tax jurisdiction of residence; and

(v) The main business activity or activities of the constituent entity.

(2) *Tax jurisdiction of residence information.* The return on Form 8975 must contain so much of the following information with respect to each tax jurisdiction in which one or more constituent entities of a U.S. MNE group is resident, presented as an aggregate of the information for the constituent entities resident in each tax jurisdiction, and in such form or manner, as Form 8975 prescribes:

(i) Revenues generated from transactions with other constituent entities;

(ii) Revenues not generated from transactions with other constituent entities;

(iii) Profit or loss before income tax;

(iv) Total income tax paid on a cash basis to all tax jurisdictions, and any taxes withheld on payments received by the constituent entities;

(v) Total accrued tax expense recorded on taxable profits or losses, reflecting only operations in the relevant annual period and excluding deferred taxes or provisions for uncertain tax liabilities;

(vi) Stated capital, except that the stated capital of a permanent establishment must be reported in the tax jurisdiction of residence of the legal entity of which it is a permanent establishment unless there is a defined capital requirement in the permanent establishment tax jurisdiction for regulatory purposes;

(vii) Total accumulated earnings, except that accumulated earnings of a permanent establishment must be reported by the legal entity of which it is a permanent establishment;

(viii) Total number of employees on a full-time equivalent basis; and

(ix) Net book value of tangible assets, which, for purposes of this section, does not include cash or cash equivalents, intangibles, or financial assets.

(3) *Special rules*—(i) *Constituent entity with no tax jurisdiction of residence.* The information listed in paragraph (d)(2) of this section also must be provided, in the aggregate, for any constituent entity or entities that have no tax jurisdiction of residence. In addition, if a constituent entity is an owner of a constituent entity that does not have a jurisdiction of tax residence, then the owner's share of such entity's revenues and profits will be aggregated with the information for the owner's tax jurisdiction of residence.

(ii) *Definition of revenue.* For purposes of this section, the term revenue includes all amounts of revenue, including revenue from sales of inventory and property, services, royalties, interest, and premiums. The term revenue does not include payments received from other constituent entities that are treated as dividends in the payor's tax jurisdiction of residence. Distributions and remittances from partnerships and other fiscally transparent entities and permanent establishments that are constituent entities are not considered revenue of the recipient-owner. The term revenue also does not include imputed earnings or deemed dividends received from other constituent entities that are taken into account solely for tax purposes and that otherwise would be included as revenue by a constituent entity. With respect to a constituent entity that is an organization exempt from taxation under section 501(a) because it is an organization described in section 501(c), 501(d), or 401(a), a state college or university described in section 511(a)(2)(B), a plan described in section 403(b) or 457(b), an individual retirement plan or annuity as defined in section 7701(a)(37), a qualified tuition program described in section 529, a qualified ABLE program described in section 529A, or a Coverdell education savings account described in section 530, the term revenue includes only revenue that is reflected in unrelated business taxable income as defined in section 512.

(iii) *Number of employees.* For purposes of this section, the number of employees on a full-time equivalent basis may be reported as of the end of the accounting period, on the basis of average employment levels for the annual accounting period, or on any other reasonable basis consistently applied across tax jurisdictions and from year to year. Independent contractors participating in the ordinary operating activities of a constituent entity may be reported as employees of such constituent entity. Reasonable rounding or approximation of the number of employees is permissible, provided that such rounding or approximation does not materially distort the relative distribution of employees across the various tax jurisdictions. Consistent approaches should be applied from year to year and across entities.

(iv) *Income tax paid and accrued tax expense of permanent establishment.* In the case of a constituent entity that is a permanent establishment, the amount of income tax paid and the amount of accrued tax expense referred to in paragraphs (d)(2)(iv) and (v) of this section should not include the income tax paid or tax expense accrued by the business entity of which the permanent establishment would be a part, but for the second sentence of paragraph (b)(2) of this section, in that business entity's tax jurisdiction of residence on the income derived by the permanent establishment.

(v) *Certain transportation income.* If a constituent entity of a U.S. MNE group derives income from international transportation or transportation in inland waterways that is covered by income tax convention provisions that are specific to such income and under which the taxing rights on such income are allocated exclusively to one tax jurisdiction, then the U.S. MNE group should report the information required under paragraph (d)(2) of this section with respect to such income for the tax jurisdiction to which the relevant income tax convention provisions allocate these taxing rights.

(e) *Reporting of financial amounts*—(1) *Reporting in U.S. dollars required.* All amounts furnished under paragraph (d)(2) of this section, other than paragraph (d)(2)(viii) of this section, must be expressed in U.S. dollars. If an exchange rate is used other than in accordance with U.S. generally accepted accounting principles for conversion to U.S. dollars, the exchange rate must be indicated.

(2) *Sources of financial amounts.* All amounts furnished under paragraph (d)(2) of this section, other than paragraph (d)(2)(viii) of this section, should be based on applicable financial statements, books and records maintained with respect to the constituent entity, regulatory financial statements, or records used for tax reporting or internal management control purposes for an annual period of each constituent entity ending with or within the period described in paragraph (c) of this section.

(f) *Time and manner for filing.* Returns on Form 8975 required under paragraph (a) of this section for a reporting period must be filed with the ultimate parent entity's income tax return for the taxable year, in or with which the reporting period ends, on or before the due date (including extensions) for filing that person's income tax return or as otherwise prescribed by Form 8975.

(g) *Maintenance of records.* The U.S. person filing Form 8975 as an ultimate parent entity of a U.S. MNE group must maintain records to support the information provided on Form 8975. However, the U.S. person is not required to create and maintain records that reconcile the amounts provided on Form 8975 with the tax returns of any tax jurisdiction or applicable financial statements.

(h) *Exceptions to furnishing information.* An ultimate parent entity of a U.S. MNE group is not required to report information under this section for the reporting period described in paragraph (c) of this section if the annual revenue of the U.S. MNE group for the immediately preceding reporting period was less than $850,000,000.

(i) [Reserved]

(j) *U.S. territories and possessions of the United States.* A U.S. territory ultimate parent entity may designate a U.S. business entity that it controls (as defined in section 6038(e)) to file Form 8975 on the U.S. territory ultimate parent entity's behalf with respect to such U.S. territory ultimate parent entity and the business entities that would be required to consolidate their accounts with such U.S. territory ultimate parent entity under U.S. generally accepted accounting principles, or would be so required if equity interests in the U.S. territory ultimate parent entity were publicly traded on a U.S. securities exchange.

(k) *Applicability dates.* The rules of this section apply to reporting periods of ultimate parent entities of U.S. MNE groups that begin on or after the first day of a taxable year of the ultimate parent entity that begins on or after June 30, 2016.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: June 20, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–15482 Filed 6–29–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Parts 20, 22, 36, 68, 71, 76, and 85

[Docket No. OAG 148; AG Order No. 3690–2016]

Civil Monetary Penalties Inflation Adjustment

AGENCY: Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: In accordance with the provisions of the Bipartisan Budget Act of 2015, the Department of Justice is adjusting for inflation civil monetary penalties assessed or enforced by components of the Department.

DATES: *Effective date:* This rule is effective August 1, 2016.

Public comments: Written comments must be postmarked and electronic comments must be submitted on or before August 29, 2016. Commenters should be aware that the electronic Federal Docket Management System (FDMS) will accept comments submitted prior to Midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. OAG 148" on all electronic and written correspondence. The Department encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at *http://*

www.regulations.gov for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW., Washington, DC 20530.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW., Washington, DC 20530, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name and address) voluntarily submitted by the commenter. You are not required to submit personal identifying information in order to comment on this rule. Nevertheless, if you want to submit personal identifying information (such as your name and address) as part of your comment, but do not want it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. Personal identifying information and confidential business information identified as set forth above will be placed in the agency's public docket file, but not posted online. If you wish to inspect the agency's public docket file in person by appointment, please see the paragraph above entitled **FOR FURTHER INFORMATION CONTACT**.

Background

A. Prior Statutory Provisions for Inflation Adjustments

The Federal Civil Monetary Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 28 U.S.C. 2461 note (2014) ("Inflation Adjustment Act"), provided for the regular evaluation and adjustment for inflation of civil monetary penalties to, among other things, ensure that they continue to maintain their deterrent effect and that penalty amounts due the Federal Government are properly accounted for and collected. Section 31001(s)(1) of the Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, also known as the Debt Collection Improvement Act of 1996 ("Improvement Act"), amended section 4 of the Inflation Adjustment Act to require the head of each agency to adjust periodically each civil monetary penalty provided by law within the jurisdiction of the Federal agency by regulation and to publish each such regulation in the **Federal Register**. Subsection (s)(1) also added a new section to the Inflation Adjustment Act providing that any increase in a civil monetary penalty made under the Act shall apply only to violations that occur after the date the increase takes effect. Subsection (s)(2) of the Improvement Act provided that the first adjustment of a civil monetary penalty made pursuant to the amendment in subsection (s)(1) may not exceed 10 percent of such penalty.

The amounts of the adjustments were determined according to a formula set forth in the Inflation Adjustment Act, which used applicable "rounders" (or increments) for calculations based on the amount of the current penalty along with the statutorily defined cost-of-living adjustment. *See* 28 CFR 85.2 (2015); Public Law 101–410, sec. 5. For example, the applicable "rounder" for a current $15,000 civil penalty amount was $5,000, which meant that there would be no inflation adjustment if the raw inflation adjustment calculation showed an increase of less than $2,500, but the civil penalty amount would be increased by the full $5,000 increment if the raw inflation adjustment was above the rounding threshold. *See id.*

B. Past Inflation Adjustment Rules

In compliance with the prior statutory requirements, the Department of Justice published a rule on February 12, 1999 (64 FR 7066–03) adjusting the immigration-related civil monetary penalties assessed or enforced by the Executive Office for Immigration Review's (EOIR) Office of the Chief Administrative Hearing Officer (OCAHO). On August 30, 1999 (64 FR 47099), the Department published a rule adjusting the other civil monetary penalties assessed or enforced by it.

On February 26, 2008 (73 FR 10130–01), the Department of Homeland Security (DHS) and the Department of Justice published a rule adjusting for inflation the immigration-related civil monetary penalties assessed or enforced by those two Departments under sections 274A, 274B, and 274C of the Immigration and Nationality Act (INA).[1] On March 28, 2014 (79 FR 17434–01), the Department published a rule adjusting for inflation the civil monetary penalties assessed or enforced by the Civil Rights Division.

C. Revised Statutory Process for Implementing Annual Inflation Adjustments

Section 701 of the Bipartisan Budget Act of 2015, Public Law 114–74 (Nov. 2, 2015), titled the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 ("2015 Amendments"), 28 U.S.C. 2461 note, substantially revised the prior provisions of the Inflation Adjustment Act and substituted a different statutory formula for calculating inflation adjustments on an annual basis.

The 2015 Amendments set forth a different method of calculation for the initial adjustment following the 2015 Amendments than for subsequent adjustments. For the initial adjustment, the "cost-of-living adjustment," which sets the amount by which the maximum civil monetary penalty or the range of minimum and maximum civil monetary penalties, as applicable, would be increased, is defined as "the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of October, 2015 exceeds the Consumer Price Index for the month of October of the calendar year during which the amount of such civil monetary penalty was established or adjusted under a provision of law other than this Act." Public Law 114–74, sec. 701(b)(2)(B) (amending section 5(b) of the Inflation Adjustment Act). This adjustment is to be applied to "the amount of the civil monetary penalty as it was most recently established or adjusted under a provision of law other than this Act," and "shall not exceed 150 percent of the amount of that civil monetary penalty on the date of enactment of" the 2015 Amendments. *Id.* For adjustments other than the initial adjustment, the "cost-of-living adjustment" is defined as "the percentage (if any) for each civil monetary penalty by which—(A) the

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[1] The former Immigration and Naturalization Service (INS) was part of the Department of Justice when the 1999 inflation adjustments rules for civil monetary penalties were adopted. However, Congress abolished the former INS effective March 1, 2003, and transferred its functions to DHS pursuant to the Homeland Security Act, Public Law 107–296 (Nov. 25, 2002). EOIR was a separate component at that time, and it remains within the Department of Justice under the authority of the Attorney General.

Consumer Price Index for the month of October preceding the date of the adjustment, exceeds (B) the Consumer Price Index 1 year before the month of October referred to in subparagraph (A)." *Id.*

In short, the 2015 Amendments tie the inflation adjustments for the initial adjustment to an index reflecting the cost of living increases between 2015 and the year in which each civil penalty was established or adjusted by a provision of law other than the Inflation Adjustment Act. For subsequent adjustments, however, the adjustment will be determined by the difference in the Consumer Price Index between the October preceding the new adjustment and the October the year before. In addition, instead of using the larger "rounders" under the old formula, the resulting new civil penalty amounts adjusted under the 2015 Amendments are rounded to the nearest $1.

The 2015 Amendments removed the 10 percent cap on the first-time inflation adjustment for each penalty, and, as noted above, provided that the initial adjustment following the 2015 Amendments "shall not exceed 150 percent of the amount of that civil monetary penalty on the date of enactment of" the 2015 Amendments. *See* Public Law 114–74, sec. 701(c) (repealing section 31001(s)(2) of the Improvement Act); *id.* sec. 701(b)(2)(B) (amending section 5(b) of the Inflation Adjustment Act). Effectively, this means that the adjusted civil penalty under this rule—which sets forth the initial inflation adjustment following the 2015 Amendments—cannot be more than 2.5 times the amount of the current penalty, including prior inflation adjustments under the Inflation Adjustment Act. As shown in Table A of this preamble indicating the calculation of inflation adjustments, this statutory cap affects only six of the civil penalties being adjusted under this rule, because of prior inflation adjustments implemented since 1999. Although the statute authorizes the Department, with the concurrence of the Director of the Office of Management and Budget, to make a determination in certain circumstances to increase a civil penalty by less than the otherwise required amount, the Department is not invoking that authority in this rule. *See* Public Law 114–74, sec. 701(b)(1)(D) (adding section 4(c) to Inflation Adjustment Act).

The 2015 Amendments also amended section 6 of the Inflation Adjustment Act to provide that "[a]ny increase under this Act in a civil monetary penalty shall apply only to civil monetary penalties, including those whose associated violation predated such increase, which are assessed after the date the increase takes effect."

Adjustments Made in This Rule for Civil Monetary Penalties

In accordance with the 2015 Amendments, the adjustments made by this rule are based on the Bureau of Labor Statistics' Consumer Price Index for October 2015. The inflation factors used in Table A were provided to all federal agencies in the OMB Memorandum for the Heads of Executive Departments and Agencies M–16–06 (Feb. 24, 2016). *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-06.pdf* (last visited June 3, 2016).

Table A provides the calculations upon which the current inflation adjustments are being made. As summarized above, the key factors for these calculations are (1) the year in which each civil penalty amount was established or adjusted under a provision of law other than the Inflation Adjustment Act; (2) the amount of each civil penalty as so established or adjusted; (3) the inflationary adjustment factor (as determined according to the chart prepared by OMB) for the year of the most recent establishment or adjustment of the amount of the penalty; and (4) the resulting amount of the new adjusted civil penalty. For example, for a civil penalty that was most recently established by law at the amount of $1,000 in the year 1996, applying the inflationary adjustment factor of 1.50245 for that year, the adjusted penalty as determined under this rule is $1,502, as rounded to the nearest $1. The only departures from this straightforward calculation are for those civil penalties whose amount was set decades ago and not previously adjusted; in those few cases, the civil penalty amount is capped at 2.5 times the civil penalty amount currently in effect, as noted by the footnotes in Table A.

TABLE A

U.S.C. Citation	Name/Description	CFR Citation	Year enacted	Last year adjusted (Non IAA)	Penalty (Non IAA) ($)	Multiplier	DOJ Penalty as of 11/2/15 ($)[1]	New DOJ penalty[2]
ATF								
18 U.S.C. 922(t)(5)	Brady Law—Nat'l Instant Criminal Check System; Transfer of firearm without checking NICS.		1993	1993	5,000	1.63238	5,000	8,162
18 U.S.C. 924(p)	Child Safety Lock Act; Secure gun storage or safety device, violation.		2005	2005	2,500	1.19397	2,500	2,985
Civil Division								
12 U.S.C. 1833a(b)(1)	Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA) Violation.	28 CFR 85.3(a)(6)	1989	1989	1,000,000	1.89361	1,100,000	1,893,610
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing) (per day)	28 CFR 85.3(a)(7)	1989	1989	1,000,000	1.89361	1,100,000	1,893,610
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing)	28 CFR 85.3(a)(7)	1989	1989	5,000,000	1.89361	5,500,000	9,468,050
22 U.S.C. 2399b(a)(3)(A)	Foreign Assistance Act; Fraudulent Claim for Assistance (per act).	28 CFR 85.3(a)(8)	1968	1968	2,000	6.73762	2,200	5,500 **
31 U.S.C. 3729(a)	False Claims Act;[3] Violations	28 CFR 85.3(a)(9)	1986	1986	Min. 5,000 Max. 10,000	2.15628	Min, 5,500 Max. 11,000	Min. 10,781 Max. 21,563
31 U.S.C. 3802(a)(1)	Program Fraud Civil Remedies Act; Violations Involving False Claim (per claim).	28 CFR 71.3(a)	1986	1986	5,000	2.15628	5,500	10,781
31 U.S.C. 3802(a)(2)	Program Fraud Civil Remedies Act; Violation Involving False Statement (per statement).	28 CFR 71.3(f)	1986	1986	5,000	2.15628	5,500	10,781
40 U.S.C. 123(a)(1)(A)	Federal Property and Administrative Services Act; Violation Involving Surplus Government Property (per act).	28 CFR 85.3(a)(12)	1949	1949	2,000	10.03536	2,200	5,500 **
41 U.S.C. 8706(a)(1)(B)	Anti-Kickback Act; Violation Involving Kickbacks[4] (per occurrence).	28 CFR 85.3(a)(13)	1986	1986	10,000	2.15628	11,000	21,563
18 U.S.C. 2723(b)	Driver's Privacy Protection Act of 1994; Prohibition on Release and Use of Certain Personal Information from State Motor Vehicle Records—Substantial Non-compliance (per day).		1994	1994	5,000	1.59089	5,000	7,954
18 U.S.C. 216(b)	Ethics Reform Act of 1989; Penalties for Conflict of Interest Crimes[5] (per violation).	28 CFR 85.3(c)	1989	1989	50,000	1.89361	55,000	94,681
41 U.S.C. 2105(b)(1)	Office of Federal Procurement Policy Act;[6] Violation by an individual (per violation).		1988	1988	50,000	1.97869	50,000	98,935
41 U.S.C. 2105(b)(2)	Office of Federal Procurement Policy Act;[6] Violation by an organization (per violation).		1988	1988	500,000	1.97869	500,000	989,345
42 U.S.C. 5157(d)	Disaster Relief Act of 1974;[7] Violation (per violation).		1974	1974	5,000	4.65436	5,000	12,500 **

Civil Rights Division (excluding immigration-related penalties)								
18 U.S.C. 248(c)(2)(B)(i)	Freedom of Access to Clinic Entrances Act of 1994 ("FACE Act"); Nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(1)(i)	1994	1994	10,000	1.59089	16,000	15,909
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(1)(ii)	1994	1994	15,000	1.59089	16,500	23,863
18 U.S.C. 248(c)(2)(B)(i)	FACE Act; Violation other than a nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(2)(i)	1994	1994	15,000	1.59089	16,500	23,863
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Violation other than a nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(2)(ii)	1994	1994	25,000	1.59089	37,500	39,772
42 U.S.C. 3614(d)(1)(C)(i)	Fair Housing Act of 1968; first violation	28 CFR 85.3(b)(3)(i)	1988	1988	50,000	1.97869	75,000	98,935
42 U.S.C. 3614(d)(1)(C)(ii)	Fair Housing Act of 1968; subsequent violation.	28 CFR 85.3(b)(3)(ii)	1988	1988	100,000	1.97869	150,000	197,869
42 U.S.C. 12188(b)(2)(C)(i)	Americans With Disabilities Act; Public accommodations for individuals with disabilities, first violation.	28 CFR 36.504(a)(3)(i)	1990	1990	50,000	1.78156	75,000	89,078
42 U.S.C. 12188(b)(2)(C)(ii)	Americans With Disabilities Act; Public accommodations for individuals with disabilities, subsequent violation.	28 CFR 36.504(a)(3)(ii)	1990	1990	100,000	1.78156	150,000	178,156
50 U.S.C. App. 597(b)(3)	Servicemembers Civil Relief Act of 2003; first violation.	28 CFR 85.3(b)(4)(i)	2010	2010	55,000	1.08745	60,000	59,810
50 U.S.C. App. 597(b)(3)	Servicemembers Civil Relief Act of 2003; subsequent violation.	28 CFR 85.3(b)(4)(ii)	2010	2010	110,000	1.08745	120,000	119,620
Criminal Division								
18 U.S.C. 983(h)(1)	Civil Asset Forfeiture Reform Act of 2000; Penalty for Frivolous Assertion of Claim.		2000	2000	Min. 250 Max. 5,000	1.36689	Min. 250 Max. 5,000	Min. 342 Max. 6,834
18 U.S.C. 1956(b)	Money Laundering Control Act of 1986; Violation[8].		1986	1986	10,000	2.15628	10,000	21,563
DEA								
21 U.S.C. 844a(a)	Anti-Drug Abuse Act of 1988; Possession of small amounts of controlled substances (per violation).	28 CFR 76.3(a)	1988	1988	10,000	1.97869	11,000	19,787
21 U.S.C. 961(1)	Controlled Substance Import Export Act; Drug abuse, import or export.	28 CFR 85.3(d)	1970	1970	25,000	6.03650	27,500	68,750 **
21 U.S.C. 842(c)(1)(A)	Controlled Substances Act ("CSA"); Violations of 842(a)—other than (5), (10) and (16)—Prohibited acts re: controlled substances (per violation).		1970	1970	25,000	6.03650	25,000	62,500 **
21 U.S.C. 842(c)(1)(B)	CSA; Violations of 842(a)(5) and (10)—Prohibited acts re: controlled substances.		1998	1998	10,000	1.45023	10,000	14,502
21 U.S.C. 842(c)(1)(C)	CSA; Violation of 825(e) by importer, exporter, manufacturer, or distributor—False labeling of anabolic steroids (per violation).		2014	2014	500,000	1.00171	500,000	500,855
21 U.S.C. 842(c)(1)(D)	CSA; Violation of 825(e) at the retail level—False labeling of anabolic steroids (per violation).		2014	2014	1,000	1.00171	1,000	1,002

TABLE A—Continued

U.S.C. Citation	Name/Description	CFR Citation	Year enacted	Last year adjusted (Non IAA)	Penalty (Non IAA) ($)	Multiplier	DOJ Penalty as of 11/2/15 ($)[1]	New DOJ penalty[2]
21 U.S.C. 842(c)(2)(C)	CSA; Violation of 842(a)(11) by a business—Distribution of laboratory supply with reckless disregard.[9]		1996	1996	250,000	1.50245	250,000	375,613
21 U.S.C. 856(d)	Illicit Drug Anti-Proliferation Act of 2003; Maintaining drug-involved premises.[10]		2003	2003	250,000	1.28561	250,000	321,403
		Immigration-Related Penalties						
8 U.S.C. 1324a(e)(4)(A)(i)	Immigration Reform and Control Act of 1986 ("IRCA"); Unlawful employment of aliens, first order (per unauthorized alien).	28 CFR 68.52(c)(1)(i)	1986	1986	Min. 250 Max. 2,000	2.15628	Min. 375 Max. 3,200	Min. 539 Max. 4,313
8 U.S.C. 1324a(e)(4)(A)(ii)	IRCA; Unlawful employment of aliens, second order (per such alien).	28 CFR 68.52(c)(1)(ii)	1986	1986	Min. 2,000 Max. 5,000	2.15628	Min. 3,200 Max. 6,500	Min. 4,313 Max. 10,781
8 U.S.C. 1324a(e)(4)(A)(iii)	IRCA; Unlawful employment of aliens, subsequent order (per such alien).	28 CFR 68.52(c)(1)(iii)	1986	1986	Min. 3,000 Max. 10,000	2.15628	Min. 4,300 Max. 16,000	Min. 6,469 Max. 21,563
8 U.S.C. 1324a(e)(5)	IRCA; Paperwork violation (per relevant individual).	28 CFR 68.52(c)(5)	1986	1986	Min. 100 Max. 1,000	2.15628	Min. 110 Max. 1,100	Min. 216 Max. 2,156
8 U.S.C. 1324a (note)	IRCA; Violation relating to participating employer's failure to notify of final nonconfirmation of employee's employment eligibility (per relevant individual).	28 CFR 68.52(c)(6)	1996	1996	Min. 500 Max. 1,000	1.50245	Min. 550 Max. 1,100	Min. 751 Max. 1,502
8 U.S.C. 1324a(g)(2)	IRCA; Violation/prohibition of indemnity bonds (per violation).	28 CFR 68.52(c)(7)	1986	1986	1,000	2.15628	1,100	2,156
8 U.S.C. 1324b(g)(2)(B)(iv)(I)	IRCA; Unfair immigration-related employment practices, first order (per individual discriminated against).	28 CFR 68.52(d)(1)(viii).	1990	1990	Min. 250 Max. 2,000	1.78156	Min, 375 Max. 3,200	Min. 445 Max. 3,563
8 U.S.C. 1324b(g)(2)(B)(iv)(II)	IRCA; Unfair immigration-related employment practices, second order (per individual discriminated against).	28 CFR 68.52(d)(1)(ix)	1990	1990	Min. 2,000 Max. 5,000	1.78156	Min. 3,200 Max. 6,500	Min. 3,563 Max. 8,908
8 U.S.C. 1324b(g)(2)(B)(iv)(III)	IRCA; Unfair immigration-related employment practices, subsequent order (per individual discriminated against).	28 CFR 68.52(d)(1)(x)	1990	1990	Min. 3,000 Max. 10,000	1.78156	Min. 4,300 Max. 16,000	Min. 5,345 Max. 17,816
8 U.S.C. 1324b(g)(2)(B)(iv)(IV)	IRCA; Unfair immigration-related employment practices, document abuse (per individual discriminated against).	28 CFR 68.52(d)(1)(xii)	1990	1990	Min. 100 Max. 1,000	1.78156	Min. 110 Max. 1,100	Min. 178 Max. 1,782
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(i)	1990	1990	Min. 250 Max. 2,000	1.78156	Min. 375 Max. 3,200	Min. 445 Max. 3,563
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(iii)	1990	1990	Min. 2,000 Max. 5,000	1.78156	Min. 3,200 Max. 6,500	Min. 3,563 Max. 8,908
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(ii)	1996	1996	Min. 250 Max. 2,000	1.50245	Min. 275 Max. 2,200	Min. 376 Max. 3,005
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(iv)	1996	1996	Min. 2,000 Max. 5,000	1.50245	Min. 2,200 Max. 5,500	Min. 3,005 Max. 7,512

				FBI				
49 U.S.C. 30505(a)	National Motor Vehicle Title Identification System; Violation (per violation).		1994	1994	1,000	1.59089	1,000	1,591
				Office of Justice Programs				
42 U.S.C. 3789g(d)	Confidentiality of information; State and Local Criminal History Record Information Systems—Right to Privacy Violation.	28 CFR 20.25	1979	1979	10,000	3.16274	11,000	27,500**

** Adjusted penalty capped at 2.5 times the penalty amount in effect on November 2, 2015, the date of enactment of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, sec. 701 ("2015 Amendments"). *See id.* § 701(b)(2) (amending section 5(b)(2)(C) of the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note) to provide that the amount of the first inflation adjustment after the date of enactment of the 2015 Amendments "shall not exceed 150 percent of the amount of that civil monetary penalty on the date of enactment of the [2015 Amendments].").

[1] The figures set forth in this column represent the penalty as last adjusted by Department of Justice regulation or statute as of November 2, 2015.

[2] All figures set forth in this table are maximum penalties, unless otherwise indicated.

[3] Section 3729(a)(1) of Title 31 states that any person who violates this section "is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. 3729(a)(1) (2012) (citation omitted). Section 3729(a)(2) permits the court to reduce the damages under certain circumstances to "not less than 2 times the amount of damages which the Government sustains because of the act of that person." *Id.* § 3729(a)(2). The adjustment made by this regulation is only applicable to the specific statutory penalty amounts stated in subsection (a)(1), which is only one component of the civil penalty imposed under section 3729(a)(1).

[4] Section 8706(a)(1) of Title 41 states that "[t]he Federal Government in a civil action may recover from a person—(1) that knowingly engages in conduct prohibited by section 8702 of this title a civil penalty equal to—(A) twice the amount of each kickback involved in the violation; and (B) not more than $10,000 for each occurrence of prohibited conduct . . . ." 41 U.S.C. 8706(a)(1) (2012). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (a)(1)(B), which is only one component of the civil penalty imposed under section 8706.

[5] Section 216(b) of Title 18 states the civil penalty should be no "more than $50,000 for each violation or the amount of compensation which the person received or offered for the prohibited conduct, whichever amount is greater." 18 U.S.C. 216(b) (2012). Therefore, the adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b), which is only one aspect of the possible civil penalty imposed under § 216(b).

[6] Section 2105(b) of Title 41 states, "(b) Civil penalties.—The Attorney General may bring a civil action in an appropriate district court of the United States against a person that engages in conduct that violates section 2102, 2103, or 2104 of this title. On proof of that conduct by a preponderance of the evidence—(1) an individual is liable to the Federal Government for a civil penalty of not more than $50,000 for each violation plus twice the amount of compensation that the individual received or offered for the prohibited conduct; and (2) an organization is liable to the Federal Government for a civil penalty of not more than $500,000 for each violation plus twice the amount of compensation that the organization received or offered for the prohibited conduct." 41 U.S.C. 2105(b) (2012). The adjustments made by this regulation are only applicable to the specific statutory penalty amounts stated in subsections (b)(1) and (b)(2), which are each only one component of the civil penalties imposed under sections 2105(b)(1) and (b)(2).

[7] The Attorney General has authority to bring a civil action when a person has violated or is about to violate a provision under this statute. 42 U.S.C. 5157(b) (2012)). The Federal Emergency Management Agency has promulgated regulations regarding this statute and has adjusted the penalty in its regulation. 44 CFR 206.14(d) (2015). The Department of Health and Human Services (HHS) has also promulgated a regulation regarding the penalty under this statute. 42 CFR 38.8 (2015).

[8] Section 1956(b)(1) of Title 18 states that "[w]hoever conducts or attempts to conduct a transaction described in subsection (a)(1) or (a)(3), or section 1957, or a transportation, transmission, or transfer described in subsection (a)(2), is liable to the United States for a civil penalty of not more than the greater of—(A) the value of the property, funds, or monetary instruments involved in the transaction; or (B) $10,000." 18 U.S.C. 1956(b)(1) (2012). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b)(1)(B), which is only one aspect of the possible civil penalty imposed under section 1956(b).

[9] Section 842(c)(2)(C) of Title 21 states that "[i]n addition to the penalties set forth elsewhere in this subchapter or subchapter II of this chapter, any business that violates paragraph (11) of subsection (a) of this section shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater." 21 U.S.C. 842(c)(2)(C) (2012). The adjustment made by this regulation regarding the penalty for a succeeding violation is only applicable to the specific statutory penalty amount stated in subsection (c)(2)(C), which is only one aspect of the possible civil penalty for a succeeding violation imposed under section 842(c)(2)(C).

[10] Section 856(d)(1) of Title 21 states that "(1) Any person who violates subsection (a) of this section shall be subject to a civil penalty of not more than the greater of—(A) $250,000; or (B) 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person." 21 U.S.C. 856(d)(1) (2012). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (d)(1)(A), which is only one aspect of the possible civil penalty imposed under section 856(d)(1).

Currently, 28 CFR 85.3 provides for inflation adjustments of a number of civil penalties enforced by the Department, pursuant to the former inflation adjustment statutory provisions. This rule revises § 85.3 to provide that the inflation adjustments set forth in that section will continue to apply to violations occurring on or before November 2, 2015, the date of enactment of the 2015 Amendments, as well as to assessments made before August 1, 2016, whose associated violations occurred after November 2, 2015. Other existing Department regulations provide for inflation adjustments of other civil penalties under prior law, such as the civil penalties under certain provisions of the immigration laws in 28 CFR 68.52. Those other existing regulations are also being revised to provide that the existing regulatory inflation adjustments will continue to apply to violations occurring on or before November 2, 2015, as well as to assessments made before August 1, 2016, whose associated violations occurred after November 2, 2015.

A new regulatory provision, § 85.5, includes a comprehensive table setting forth the penalty amounts for civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015. The table in § 85.5 is the same as Table A in this preamble, except that it only includes the first three descriptive columns for each civil penalty provision, and the last two columns setting forth the penalty amounts in effect on November 2, 2015 (the date of enactment of the 2015 Amendments) and the new adjusted civil penalty amounts taking effect for civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015. (The other columns in Table A, which show how the adjusted civil penalty amounts are calculated, are provided for informational purposes in this preamble, but are not being codified in the Code of Federal Regulations.) Those instances where the civil penalty amount for the initial adjustment is capped at 2.5 times the civil penalty amount currently in effect, as provided in the 2015 Amendments, are noted by footnote in the table in § 85.5.[2]

This rule adjusts for inflation civil monetary penalties within the jurisdiction of the Justice Department for purposes of the Inflation Adjustment Act, as amended. Other agencies are responsible for the inflation adjustments of certain other civil monetary penalties that the Department's litigating components bring suit to collect. The reader should consult the regulations of those other agencies for inflation adjustments to those penalties.

Effective Date of Adjusted Civil Penalty Amounts

In this rule, the adjusted civil penalty amounts are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, the date of enactment of the 2015 Amendments. Therefore, violations occurring on or before November 2, 2015, and assessments made prior to August 1, 2016, whose associated violations occurred after November 2, 2015, will continue to be subject to the civil monetary penalty amounts set forth in the Department's existing regulations in 28 CFR parts 20, 22, 36, 68, 71, 76 and 85 (or as set forth by statute if the amount has not yet been adjusted by regulation).

Statutory and Regulatory Analyses

Administrative Procedure Act, 5 U.S.C. 553

The Attorney General is publishing this rule as an interim final rule, without prior notice and comment, as authorized by the 2015 Amendments. The Department is providing a 60-day period for public comment after publication of this rule and welcomes public comment on the changes made to reflect the revised process for calculating inflation adjustments under the Inflation Adjustment Act, as amended by the 2015 Amendments.

Regulatory Flexibility Act

Only those entities that are determined to have violated Federal law and regulations would be affected by the increase in the civil penalty amounts made by this rule. A Regulatory Flexibility Act analysis is not required for this rule because publication of a notice of proposed rulemaking is not required. *See* 5 U.S.C. 603(a).

Executive Orders 12866 and 13563—Regulatory Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review" section 1(b), The Principles of Regulation, and in accordance with Executive Order 13563, "Improving Regulation and Regulatory Review" section 1, General Principles of Regulation.

The Department of Justice has determined that this rule is not a "significant regulatory action" under Executive Order 12866, Regulatory Planning and Review, section 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

Both Executive Orders 12866 and 13563 direct agencies, in certain circumstances, to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). As stated above, the statute authorizes the Department, with the concurrence of the Director of the Office of Management and Budget, to make a determination in certain circumstances to increase a civil penalty by less than the otherwise required amount. However, the Department is not invoking that authority in this rule. The adjustments to existing civil monetary penalties set forth in this rule are calculated pursuant to the statutory formula.

Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

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[2] In rare instances, the adjusted civil penalty amount under this rule is less than the penalty amount currently in effect, because, in these cases, the use of rounders under the former law increased a particular penalty by an increment exceeding the actual rate of inflation. For example, in 2014, the Department published a rule increasing the $55,000 civil penalty for a first violation of the Servicemembers Civil Relief Act, 50 U.S.C. 4041(b)(3), by an increment of $5,000 to $60,000. 79 FR 17434–01 (Mar. 28, 2014). Under this rule, taking account of the actual rate of inflation since enactment, the civil penalty amount is adjusted slightly lower to $59,810.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. It will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects

28 CFR Part 20

Classified information, Crime, Intergovernmental relations, Investigations, Law Enforcement, Penalties, Privacy, Research, and Statistics.

28 CFR Part 22

Crime, Juvenile delinquency, Penalties, Privacy, Research, and Statistics.

28 CFR Part 36

Administrative practice and procedure, Alcoholism, Americans with disabilities, Buildings and facilities, Business and industry, Civil rights, Consumer protection, Drug abuse, Handicapped, Historic preservation, Individuals with disabilities, Penalties, Reporting and recordkeeping requirements.

28 CFR Part 68

Administrative practice and procedure, Aliens, Citizenship and naturalization, Civil rights, Discrimination in employment, Employment, Equal employment opportunity, Immigration, Nationality, Non-discrimination.

28 CFR Part 71

Administrative practice and procedure, Claims, Fraud, Organization and function (Government agencies), Penalties.

28 CFR Part 76

Administrative practice and procedure, Drug abuse, Drug traffic control, Penalties.

28 CFR Part 85

Administrative practice and procedure, Penalties.

Accordingly, for the reasons set forth in the preamble, chapter I of Title 28 of the Code of Federal Regulations is amended as follows:

PART 20—CRIMINAL JUSTICE INFORMATION SYSTEMS

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 28 U.S.C. 534; Pub. L. 92–544, 86 Stat. 1115; 42 U.S.C. 3711, *et seq.*; Pub. L. 99–169, 99 Stat. 1002, 1008–1011, as amended by Pub. L. 99–569, 100 Stat. 3190, 3196; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321.

■ 2. In § 20.25, add after the first sentence a new sentence to read as follows:

§ 20.25 Penalties.

* * * For civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, see the civil penalty amount as provided in 28 CFR 85.5. * * *

PART 22—CONFIDENTIALITY OF IDENTIFIABLE RESEARCH AND STATISTICAL INFORMATION

■ 3. The authority citation for part 22 continues to read as follows:

Authority: Secs. 801(a), 812(a), Omnibus Crime Control and Safe Streets Act of 1968, 42 U.S.C. 3701, *et seq.*, as amended (Pub. L. 90–351, as amended by Pub. L. 93–83, Pub. L. 93–415, Pub. L. 94–430, Pub. L. 94–503, Pub. L. 95–115, Pub. L. 96–157, and Pub. L. 98–473); secs. 262(b), 262(d), Juvenile Justice and Delinquency Prevention Act of 1974, 42 U.S.C. 5601, *et seq.*, as amended (Pub. L. 93–415, as amended by Pub. L. 94–503, Pub. L. 95–115, Pub. L. 99–509, and Pub. L. 98–473); and secs. 1407(a) and 1407(d) of the Victims of Crime Act of 1984, 42 U.S.C. 10601, *et seq.*, Pub. L. 98–473; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321.

■ 4. In § 22.29 add a new sentence at the end to read as follows:

§ 22.29 Sanctions.

* * * For civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, see the civil penalty amount as provided in 28 CFR 85.5.

PART 36—NONDISCRIMINATION ON THE BASIS OF DISABILITY BY PUBLIC ACCOMMODATIONS AND IN COMMERCIAL FACILITIES

■ 5. The authority citation for part 36 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510; 42 U.S.C. 12188(b); Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321.

■ 6. In § 36.504, revise paragraphs (a)(3)(i) and (a)(3)(ii), to read as follows:

§ 36.504 Relief.

(a) * * *

(3) * * *

(i) Not exceeding $50,000 for a first violation occurring before September 29, 1999, and not exceeding $55,000 for a first violation occurring on or after September 29, 1999, and before April 28, 2014, and not exceeding $75,000 for a first violation occurring on or after April 28, 2014, except that, for civil penalties assessed after August 1, 2016, for a first violation occurring after November 2, 2015, the civil penalty shall not exceed the applicable amount set forth in 28 CFR 85.5.

(ii) Not exceeding $100,000 for any subsequent violation occurring before September 29, 1999, and not exceeding $110,000 for any subsequent violation occurring on or after September 29, 1999, and before April 28, 2014, and not exceeding $150,000 for any subsequent violation occurring on or after April 28, 2014, except that, for civil penalties assessed after August 1, 2016, for any subsequent violation occurring after November 2, 2015, the civil penalty shall not exceed the applicable amount set forth in 28 CFR 85.5.

* * * * *

PART 68—RULES OF PRACTICE AND PROCEDURE FOR ADMINISTRATIVE HEARINGS BEFORE ADMINISTRATIVE LAW JUDGES IN CASES INVOLVING ALLEGATIONS OF UNLAWFUL EMPLOYMENT OF ALIENS, UNFAIR IMMIGRATION-RELATED EMPLOYMENT PRACTICES, AND DOCUMENT FRAUD

■ 7. The authority citation for part 68 continues to read as follows:

Authority: 5 U.S.C. 301, 554; 8 U.S.C. 1103, 1324a, 1324b, and 1324c.

■ 8. In § 68.52, revise paragraphs (c)(8), (d)(2), and (e)(3), to read as follows:

§ 68.52 Final order of the Administrative Law Judge.

* * * * *

(c) * * *

(8) *Civil penalties assessed after August 1, 2016.* For civil penalties assessed after August 1, 2016, whose associated violations described in paragraph (c) of this section occurred after November 2, 2015, the applicable civil penalty amounts are set forth in 28 CFR 85.5.

* * * * *

(d) * * *

(2) *Civil penalties assessed after August 1, 2016.* For civil penalties assessed after August 1, 2016, whose associated violations described in paragraph (d) of this section occurred

after November 2, 2015, the applicable civil penalty amounts are set forth in 28 CFR 85.5.

* * * * *

(e) * * *

(3) *Civil penalties assessed after August 1, 2016.* For civil penalties assessed after August 1, 2016, whose associated violations described in paragraph (e) of this section occurred after November 2, 2015, the applicable civil penalty amounts are set forth in 28 CFR 85.5.

* * * * *

PART 71—IMPLEMENTATION OF THE PROVISIONS OF THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

■ 9. The authority citation for part 71 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510; 31 U.S.C. 3801–3812; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321.

■ 10. In § 71.3, paragraph (a) introductory text and paragraph (f) introductory text are revised, to read as follows:

§ 71.3 Basis for civil penalties and assessments.

(a) Any person shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,000 for each claim listed in paragraphs (a)(1) through (a)(4) of this section made before September 29, 1999, and not more than $5,500 for each such claim made on or after September 29, 1999, and not more than the applicable amount as provided in 28 CFR 85.5 for civil penalties assessed after August 1, 2016, for each such claim made after November 2, 2015, if that person makes a claim that the person knows or has reason to know:

* * * * *

(f) Any person shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,000 for each statement listed in paragraphs (f)(1) and (f)(2) of this section made before September 29, 1999, and not more than $5,500 for each such statement made on or after September 29, 1999, and not more than the applicable amount as provided in 28 CFR 85.5 for civil penalties assessed after August 1, 2016 for each such statement made after November 2, 2015, if that person makes a written statement that:

* * * * *

PART 76—RULES OF PROCEDURE FOR ASSESSMENT OF CIVIL PENALTIES FOR POSSESSION OF CERTAIN CONTROLLED SUBSTANCES

■ 11. The authority citation for part 76 continues to read as follows:

Authority: 5 U.S.C. 301; 21 U.S.C. 844a, 875, 876; 28 U.S.C. 509, 510; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321.

■ 12. In § 76.3 add a new sentence at the end of paragraph (a) to read as follows:

§ 76.3 Basis for civil penalty.

(a) * * * For civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, see the civil penalty amount as provided in 28 CFR 85.5.

* * * * *

PART 85—CIVIL MONETARY PENALTIES INFLATION ADJUSTMENT

■ 13. The authority citation for part 85 is revised to read as follows:

Authority: 5 U.S.C. 301, 28 U.S.C. 503; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321; Pub. L. 114–74, section 701, 28 U.S.C. 2461 note.

■ 14. Revise § 85.1 to read as follows:

§ 85.1 In general.

(a) For violations occurring on or before November 2, 2015, and for civil penalties assessed before August 1, 2016, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department of Justice and listed in section 85.3 are adjusted as set forth in that section, in accordance with the requirements of the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 104–410, 104 Stat. 890, in effect prior to November 2, 2015.

(b) For civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department of Justice are adjusted as set forth in section 85.5, in accordance with the requirements of the Bipartisan Budget Act of 2015, Public Law 114–74, section 701 (Nov. 2, 2015), 28 U.S.C. 2461 note.

§ 85.2 [Removed and reserved]

■ 15. Remove and reserve § 85.2.

■ 16. In § 85.3, revise the heading and the introductory text to read as follows:

§ 85.3 Adjustments to penalties for violations occurring on or before November 2, 2015.

For all violations occurring on or before November 2, 2015, and for assessments made before August 1, 2016, for violations occurring after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the respective components of the Department, as set forth in paragraphs (a) through (d) of this section, are adjusted as provided in this section in accordance with the inflation adjustment procedures prescribed in section 5 of the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, as in effect prior to November 2, 2015. The adjusted penalties set forth in paragraphs (a), (c), and (d) of this section are effective for violations occurring on or after September 29, 1999, and on or before November 2, 2015, and for assessments made before August 1, 2016, for violations occurring after November 2, 2015. For civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, see the adjusted penalty amounts in section 85.5.

* * * * *

■ 17. Add § 85.5 to read as follows:

§ 85.5 Adjustments to penalties for violations occurring after November 2, 2015.

For civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are adjusted as set forth in the following table.

U.S.C. Citation	Name/Description	CFR Citation	DOJ Penalty as of 11/2/15 ($)[1]	New DOJ penalty[2]
		ATF		
18 U.S.C. 922(t)(5)	Brady Law—Nat'l Instant Criminal Check System; Transfer of firearm without checking NICS.		5,000	8,162

U.S.C. Citation	Name/Description	CFR Citation	DOJ Penalty as of 11/2/15 ($) [1]	New DOJ penalty [2]
18 U.S.C. 924(p)	Child Safety Lock Act; Secure gun storage or safety device, violation.		2,500	2,985
Civil Division				
12 U.S.C. 1833a(b)(1)	Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA) Violation.	28 CFR 85.3(a)(6)	1,100,000	1,893,610
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing) (per day)	28 CFR 85.3(a)(7)	1,100,000	1,893,610
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing)	28 CFR 85.3(a)(7)	5,500,000	9,468,050
22 U.S.C. 2399b(a)(3)(A)	Foreign Assistance Act; Fraudulent Claim for Assistance (per act).	28 CFR 85.3(a)(8)	2,200	5,500 **
31 U.S.C. 3729(a)	False Claims Act; [3] Violations	28 CFR 85.3(a)(9)	Min, 5,500 Max. 11,000	Min. 10,781 Max. 21,563
31 U.S.C. 3802(a)(1)	Program Fraud Civil Remedies Act; Violations Involving False Claim (per claim).	28 CFR 71.3(a)	5,500	10,781
31 U.S.C. 3802(a)(2)	Program Fraud Civil Remedies Act; Violation Involving False Statement (per statement).	28 CFR 71.3(f)	5,500	10,781
40 U.S.C. 123(a)(1)(A)	Federal Property and Administrative Services Act; Violation Involving Surplus Government Property (per act).	28 CFR 85.3(a)(12)	2,200	5,500 **
41 U.S.C. 8706(a)(1)(B)	Anti-Kickback Act; Violation Involving Kickbacks [4] (per occurrence).	28 CFR 85.3(a)(13)	11,000	21,563
18 U.S.C. 2723(b)	Driver's Privacy Protection Act of 1994; Prohibition on Release and Use of Certain Personal Information from State Motor Vehicle Records—Substantial Non-compliance (per day).		5,000	7,954
18 U.S.C. 216(b)	Ethics Reform Act of 1989; Penalties for Conflict of Interest Crimes [5] (per violation).	28 CFR 85.3(c)	55,000	94,681
41 U.S.C. 2105(b)(1)	Office of Federal Procurement Policy Act; [6] Violation by an individual (per violation).		50,000	98,935
41 U.S.C. 2105(b)(2)	Office of Federal Procurement Policy Act; [6] Violation by an organization (per violation).		500,000	989,345
42 U.S.C. 5157(d)	Disaster Relief Act of 1974; [7] Violation (per violation)		5,000	12,500 **
Civil Rights Division (excluding immigration-related penalties)				
18 U.S.C. 248(c)(2)(B)(i)	Freedom of Access to Clinic Entrances Act of 1994 ("FACE Act"); Nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(1)(i)	16,000	15,909
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(1)(ii)	16,500	23,863
18 U.S.C. 248(c)(2)(B)(i)	FACE Act; Violation other than a nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(2)(i)	16,500	23,863
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Violation other than a nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(2)(ii)	37,500	39,772
42 U.S.C. 3614(d)(1)(C)(i)	Fair Housing Act of 1968; first violation	28 CFR 85.3(b)(3)(i)	75,000	98,935
42 U.S.C. 3614(d)(1)(C)(ii)	Fair Housing Act of 1968; subsequent violation	28 CFR 85.3(b)(3)(ii)	150,000	197,869
42 U.S.C. 12188(b)(2)(C)(i).	Americans With Disabilities Act; Public accommodations for individuals with disabilities, first violation.	28 CFR 36.504(a)(3)(i)	75,000	89,078
42 U.S.C. 12188(b)(2)(C)(ii).	Americans With Disabilities Act; Public accommodations for individuals with disabilities, subsequent violation.	28 CFR 36.504(a)(3)(ii)	150,000	178,156
50 U.S.C. App. 597(b)(3)	Servicemembers Civil Relief Act of 2003; first violation.	28 CFR 85.3(b)(4)(i)	60,000	59,810
50 U.S.C. App. 597(b)(3)	Servicemembers Civil Relief Act of 2003; subsequent violation.	28 CFR 85.3(b)(4)(ii)	120,000	119,620
Criminal Division				
18 U.S.C. 983(h)(1)	Civil Asset Forfeiture Reform Act of 2000; Penalty for Frivolous Assertion of Claim.		Min. 250 Max. 5,000	Min. 342 Max. 6,834
18 U.S.C. 1956(b)	Money Laundering Control Act of 1986; Violation [8]		10,000	21,563
DEA				
21 U.S.C. 844a(a)	Anti-Drug Abuse Act of 1988; Possession of small amounts of controlled substances (per violation).	28 CFR 76.3(a)	11,000	19,787
21 U.S.C. 961(1)	Controlled Substance Import Export Act; Drug abuse, import or export.	28 CFR 85.3(d)	27,500	68,750 **

U.S.C. Citation	Name/Description	CFR Citation	DOJ Penalty as of 11/2/15 ($) [1]	New DOJ penalty [2]
21 U.S.C. 842(c)(1)(A)	Controlled Substances Act ("CSA"); Violations of 842(a)—other than (5), (10) and (16)—Prohibited acts re: controlled substances (per violation).		25,000	62,500 **
21 U.S.C. 842(c)(1)(B)	CSA; Violations of 842(a)(5) and (10)—Prohibited acts re: controlled substances.		10,000	14,502
21 U.S.C. 842(c)(1)(C)	CSA; Violation of 825(e) by importer, exporter, manufacturer, or distributor—False labeling of anabolic steroids (per violation).		500,000	500,855
21 U.S.C. 842(c)(1)(D)	CSA; Violation of 825(e) at the retail level—False labeling of anabolic steroids (per violation).		1,000	1,002
21 U.S.C. 842(c)(2)(C)	CSA; Violation of 842(a)(11) by a business—Distribution of laboratory supply with reckless disregard [9].		250,000	375,613
21 U.S.C. 856(d)	Illicit Drug Anti-Proliferation Act of 2003; Maintaining drug-involved premises [10].		250,000	321,403
	Immigration-Related Penalties			
8 U.S.C. 1324a(e)(4)(A)(i)	Immigration Reform and Control Act of 1986 ("IRCA"); Unlawful employment of aliens, first order (per unauthorized alien).	28 CFR 68.52(c)(1)(i)	Min. 375 Max 3,200	Min. 539 Max. 4,313
8 U.S.C. 1324a(e)(4)(A)(ii)	IRCA; Unlawful employment of aliens, second order (per such alien).	28 CFR 68.52(c)(1)(ii)	Min. 3,200 Max. 6,500	Min. 4,313 Max. 10,781
8 U.S.C. 1324a(e)(4)(A)(iii)	IRCA; Unlawful employment of aliens, subsequent order (per such alien).	28 CFR 68.52(c)(1)(iii)	Min. 4,300 Max. 16,000	Min. 6,469 Max. 21,563
8 U.S.C. 1324a(e)(5)	IRCA; Paperwork violation (per relevant individual)	28 CFR 68.52(c)(5)	Min. 110 Max. 1,100	Min. 216 Max. 2,156
8 U.S.C. 1324a (note)	IRCA; Violation relating to participating employer's failure to notify of final nonconfirmation of employee's employment eligibility (per relevant individual).	28 CFR 68.52(c)(6)	Min. 550 Max. 1,100	Min. 751 Max. 1,502
8 U.S.C. 1324a(g)(2)	IRCA; Violation/prohibition of indemnity bonds (per violation).	28 CFR 68.52(c)(7)	1,100	2,156
8 U.S.C. 1324b(g)(2)(B)(iv)(I).	IRCA; Unfair immigration-related employment practices, first order (per individual discriminated against).	28 CFR 68.52(d)(1)(viii)	Min, 375 Max. 3,200	Min. 445 Max. 3,563
8 U.S.C. 1324b(g)(2)(B)(iv)(II).	IRCA; Unfair immigration-related employment practices, second order (per individual discriminated against).	28 CFR 68.52(d)(1)(ix)	Min. 3,200 Max. 6,500	Min. 3,563 Max. 8,908
8 U.S.C. 1324b(g)(2)(B)(iv)(III).	IRCA; Unfair immigration-related employment practices, subsequent order (per individual discriminated against).	28 CFR 68.52(d)(1)(x)	Min. 4,300 Max. 16,000	Min. 5,345 Max. 17,816
8 U.S.C. 1324b(g)(2)(B)(iv)(IV).	IRCA; Unfair immigration-related employment practices, document abuse (per individual discriminated against).	28 CFR 68.52(d)(1)(xii)	Min. 110 Max. 1,100	Min. 178 Max. 1,782
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(i)	Min. 375 Max. 3,200	Min. 445 Max. 3,563
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(iii)	Min. 3,200 Max. 6,500	Min. 3,563 Max. 8,908
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(ii)	Min. 275 Max. 2,200	Min. 376 Max. 3,005
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(iv)	Min. 2,200 Max. 5,500	Min. 3,005 Max. 7,512
	FBI			
49 U.S.C. 30505(a)	National Motor Vehicle Title Identification System; Violation (per violation).		1,000	1,591

U.S.C. Citation	Name/Description	CFR Citation	DOJ Penalty as of 11/2/15 ($)[1]	New DOJ penalty[2]
Office of Justice Programs				
42 U.S.C. 3789g(d)	Confidentiality of Information; State and Local Criminal History Record Information Systems—Right to Privacy Violation.	28 CFR 20.25	11,000	27,500**

** Adjusted penalty capped at 2.5 times the penalty amount in effect on November 2, 2015, the date of enactment of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, sec. 701 ("2015 Amendments"). *See id.* § 701(b)(2) (amending section 5(b)(2)(C) of the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note) to provide that the amount of the first inflation adjustment after the date of enactment of the 2015 Amendments "shall not exceed 150 percent of the amount of that civil monetary penalty on the date of enactment of the [2015 Amendments].").

[1] The figures set forth in this column represent the penalty as last adjusted by Department of Justice regulation or statute as of November 2, 2015.

[2] All figures set forth in this table are maximum penalties, unless otherwise indicated.

[3] Section 3729(a)(1) of Title 31 states that any person who violates this section "is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. 3729(a)(1) (2012) (citation omitted). Section 3729(a)(2) permits the court to reduce the damages under certain circumstances to "not less than 2 times the amount of damages which the Government sustains because of the act of that person." *Id.* § 3729(a)(2). The adjustment made by this regulation is only applicable to the specific statutory penalty amounts stated in subsection (a)(1), which is only one component of the civil penalty imposed under section 3729(a)(1).

[4] Section 8706(a)(1) of Title 41 states that "[t]he Federal Government in a civil action may recover from a person—(1) that knowingly engages in conduct prohibited by section 8702 of this title a civil penalty equal to—(A) twice the amount of each kickback involved in the violation; and (B) not more than $10,000 for each occurrence of prohibited conduct . . . ." 41 U.S.C. 8706(a)(1) (2012). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (a)(1)(B), which is only one component of the civil penalty imposed under section 8706.

[5] Section 216(b) of Title 18 states the civil penalty should be no "more than $50,000 for each violation or the amount of compensation which the person received or offered for the prohibited conduct, whichever amount is greater." 18 U.S.C. 216(b) (2012). Therefore, the adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b), which is only one aspect of the possible civil penalty imposed under § 216(b).

[6] Section 2105(b) of Title 41 states, "(b) Civil penalties.—The Attorney General may bring a civil action in an appropriate district court of the United States against a person that engages in conduct that violates section 2102, 2103, or 2104 of this title. On proof of that conduct by a preponderance of the evidence—(1) an individual is liable to the Federal Government for a civil penalty of not more than $50,000 for each violation plus twice the amount of compensation that the individual received or offered for the prohibited conduct; and (2) an organization is liable to the Federal Government for a civil penalty of not more than $500,000 for each violation plus twice the amount of compensation that the organization received or offered for the prohibited conduct." 41 U.S.C. 2105(b) (2012). The adjustments made by this regulation are only applicable to the specific statutory penalty amounts stated in subsections (b)(1) and (b)(2), which are each only one component of the civil penalties imposed under sections 2105(b)(1) and (b)(2).

[7] The Attorney General has authority to bring a civil action when a person has violated or is about to violate a provision under this statute. 42 U.S.C. 5157(b) (2012)). The Federal Emergency Management Agency has promulgated regulations regarding this statute and has adjusted the penalty in its regulation. 44 CFR 206.14(d) (2015). The Department of Health and Human Services (HHS) has also promulgated a regulation regarding the penalty under this statute. 42 CFR 38.8 (2015).

[8] Section 1956(b)(1) of Title 18 states that "[w]hoever conducts or attempts to conduct a transaction described in subsection (a)(1) or (a)(3), or section 1957, or a transportation, transmission, or transfer described in subsection (a)(2), is liable to the United States for a civil penalty of not more than the greater of—(A) the value of the property, funds, or monetary instruments involved in the transaction; or (B) $10,000." 18 U.S.C. 1956(b)(1) (2012). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b)(1)(B), which is only one aspect of the possible civil penalty imposed under section 1956(b).

[9] Section 842(c)(2)(C) of Title 21 states that "[i]n addition to the penalties set forth elsewhere in this subchapter or subchapter II of this chapter, any business that violates paragraph (11) of subsection (a) of this section shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater." 21 U.S.C. 842(c)(2)(C) (2012). The adjustment made by this regulation regarding the penalty for a succeeding violation is only applicable to the specific statutory penalty amount stated in subsection (c)(2)(C), which is only one aspect of the possible civil penalty for a succeeding violation imposed under section 842(c)(2)(C).

[10] Section 856(d)(1) of Title 21 states that "(1) Any person who violates subsection (a) of this section shall be subject to a civil penalty of not more than the greater of—(A) $250,000; or (B) 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person." 21 U.S.C. 856(d)(1) (2012). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (d)(1)(A), which is only one aspect of the possible civil penalty imposed under section 856(d)(1).

Dated: June 24, 2016.

Loretta E. Lynch,

Attorney General.

[FR Doc. 2016–15528 Filed 6–29–16; 8:45 am]

BILLING CODE 4410–19–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

RIN 1506–AB33

Civil Monetary Penalty Adjustment and Table

AGENCY: Financial Crimes Enforcement Network ("FinCEN"), Treasury.

ACTION: Interim final rule.

SUMMARY: FinCEN is amending the regulations under the Bank Secrecy Act to adjust the maximum amount or range, as set by statute, of certain civil monetary penalties within its jurisdiction to account for inflation. This action is being taken to implement the requirements of the Federal Civil Penalties Inflation Adjustment Act of 1990, as further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: *Effective Date:* August 1, 2016.

Comment date: Written comments on this Interim Final Rulemaking must be submitted on or before August 1, 2016.

ADDRESSES: Comments may be submitted, identified by Regulatory

Identification Number (RIN) 1506–AB33, by any of the following methods:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Include RIN 1506–AB33 in the submission. Refer to Docket Number FINCEN–2014–0005.
- *Mail:* FinCEN, P.O. Box 39, Vienna, VA 22183. Include RIN 1506–AB33 in the body of the text.

Please submit comments by one method only. Comments submitted in response to this interim final rulemaking will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

Inspection of comments: The public dockets for FinCEN can be found at *Regulations.gov.* **Federal Register** notices published by FinCEN are searchable by docket number, RIN, or document title, among other things, and the docket number, RIN, and title may be found at the beginning of the notice. FinCEN uses the electronic, Internet-accessible dockets at *Regulations.gov* as their complete, official-record docket; all hard copies of materials that should be in the docket, including public comments, are electronically scanned and placed in the docket. In general, FinCEN will make all comments publicly available by posting them on *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at (800) 767–2825 or email *frc@fincen.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, ("FCPIA Act"), as further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the "2015 Act"), requires each Federal agency to adjust its civil monetary penalties within its jurisdiction for inflation annually. Specifically, the FCPIA Act now requires agencies to adjust the level of civil monetary penalties with an initial "catch-up" adjustment through an interim final rulemaking, and to make subsequent annual adjustments for inflation. The adjustment is based on the formula described in section 5(b) of the FCPIA Act. Increases are rounded to the nearest multiple of $1.

To calculate the catch-up adjustment, agencies must identify, for each penalty subject to the FCPIA Act, the year and corresponding amount(s) for which the maximum penalty or range of minimum and maximum penalties was established or last adjusted, whichever is later. Agencies will adjust the penalty amount or range of penalty amounts based on the Consumer Price Index for all Urban Consumers ("CPI–U") for the month of October 2015 using an inflation factor, or multiplier, that reflects the CPI–U increase for the year in which the maximum penalty or range of penalties was established or last adjusted.[1] For the first penalty adjustment after the effective date of the 2015 Act, the amount of the increase shall not exceed 150 percent of the amount of a civil monetary penalty on November 2, 2015, the date of the enactment of the 2015 Act.

Subsequent annual inflation adjustments will be based on any percentage change between the October CPI–U preceding the date of the adjustment, and the prior year's October CPI–U.

FinCEN is authorized to impose civil monetary penalties for violations of the Bank Secrecy Act and its implementing regulations. Several of those penalties, such as the penalty under 31 U.S.C. 5321(a)(2), are not subject to adjustment under the FCPIA Act because they lack a stated dollar amount and are instead written solely as functions of violations. The penalties subject to adjustment under the FCPIA Act are as follows:

- 12 U.S.C. 1829b(j), relating to recordkeeping violations for funds transfers. The $10,000 penalty amount set out in 12 U.S.C. 1929b(j) was last adjusted by statute in 1988. The inflation factor for 1988 is 1.97869. Multiplying the penalty amount of $10,000 by the inflation factor of 1.97869 results in an inflation adjusted maximum penalty amount of $19,787, when rounded to the nearest dollar.
- 12 U.S.C. 1955, relating to willful or grossly negligent recordkeeping violations. The $10,000 penalty amount set out in 12 U.S.C. 1955 was last adjusted by statute in 1988. The inflation factor for 1988 is 1.97869. Multiplying the penalty amount of $10,000 by the inflation factor of 1.97869 results in an inflation adjusted maximum penalty amount of $19,787, when rounded to the nearest dollar.
- 31 U.S.C. 5318(k)(3)(C), relating to failures to terminate correspondent relationships with a foreign bank. The $10,000 penalty amount set out in 31 U.S.C. 5318(k)(3)(C) was last adjusted by statute in 2001. The inflation factor for 2001 is 1.33842. Multiplying the current maximum penalty amount of $10,000 by the inflation factor of 1.33842 results in an inflation-adjusted maximum penalty amount of $13,384, when rounded to the nearest dollar.
- 31 U.S.C. 5321(a)(1), relating to willful violations of Bank Secrecy Act requirements. The minimum and maximum amounts of $25,000 and $100,000 set out in 31 U.S.C. 5321(a)(1) were last adjusted by statute in 1986. The inflation factor for 1986 is 2.15628. Multiplying the current minimum and maximum penalty amounts of $25,000 and $100,000 by the inflation factor of 2.15628 results in an inflation-adjusted range of minimum and maximum penalty amounts of $53,907 and $215,628, respectively, when rounded to the nearest dollar.
- 31 U.S.C. 5321(a)(5)(B)(i), relating to non-willful violations of foreign financial agency transactions. The $10,000 amount set out in 31 U.S.C. 5312(a)(5)(B)(i) was last adjusted by statute in 2004. The inflation factor for 2004 is 1.24588. Multiplying the current maximum penalty amount of $10,000 by the inflation factor of 1.24588 results in an inflation-adjusted maximum penalty of $12,459, when rounded to the nearest dollar.
- 31 U.S.C. 5321(a)(5)(C), relating to willful violations of foreign financial agency transactions. The $100,000 amount set out in 31 U.S.C. 5321(a)(5)(C) was last adjusted by statute in 2004. The inflation factor for 2004 is 1.24588. Multiplying the current maximum penalty amount of $100,000 by the inflation factor of 1.24588 results in an inflation-adjusted maximum penalty amount of $124,588, when rounded to the nearest dollar.
- 31 U.S.C. 5321(a)(6)(A), relating to negligent violations by a financial institution or non-financial trade or business. The $500 amount set out in 31 U.S.C. 5321(a)(6)(A) was last adjusted by statute in 1986. The inflation factor for 1986 is 2.15628. Multiplying the current maximum penalty amount of $500 by the inflation factor of 2.15628 results in an inflation-adjusted maximum penalty amount of $1,078, when rounded to the nearest dollar.
- 31 U.S.C. 5321(a)(6)(B), relating to a pattern of negligent activity by a financial institution or non-financial trade or business. The $50,000 penalty amount set out in 31 U.S.C. 5321(a)(6)(B) was last adjusted by statute in 1992. The inflation factor for 1992 is 1.67728. Multiplying the current maximum penalty amount of $50,000 by the inflation factor of 1.67728 results in an inflation-adjusted maximum penalty amount of $83,864, when rounded to the nearest dollar.

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[1] OMB Memorandum M–16–06, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, February 24, 2014 sets forth inflation factors. See, *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-06.pdf.*

- 31 U.S.C. 5321(a)(7), relating to violations of due diligence requirements for private banking accounts or correspondent bank accounts involving foreign persons, the prohibition on correspondent accounts for shell banks, and any special measure. The $1,000,000 amount set out in 31 U.S.C. 5321(a)(7) was last adjusted by statute in 2001. The inflation factor for 2001 is 1.33842. Multiplying the current maximum penalty amount of $1,000,000 by the inflation factor of 1.33842 results in an inflation-adjusted maximum penalty amount of $1,338,420, when rounded to the nearest dollar.
- 31 U.S.C. 5330(e), relating to the failure to register as a money transmitting business. The $5,000 penalty amount set out in 31 U.S.C. 5330(e) was last adjusted by statute in 1994. The inflation factor for 1994 is 1.59089. Multiplying the current penalty amount of $5,000 by the inflation factor of 1.59089 results in an inflation-adjusted penalty amount of $7,954, when rounded to the nearest dollar.

The adjusted civil penalty amounts described in this rule are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, the date of enactment of the 2015 Amendments. Therefore, violations occurring on or before November 2, 2015, and assessments made prior to August 1, 2016 whose associated violations occurred after November 2, 2015, will continue to be subject to the civil monetary penalty amounts set forth in FinCEN's existing regulations.

II. Request for Comment

FinCEN invites comment on any and all aspects of the interim final rule.

III. Effective Date

The FCPIA Act mandates that inflation adjustments to civil monetary penalties be published through an interim final rulemaking to be published by July 1, 2016, and that the inflation-adjusted civil monetary penalties take effect not later than August 1, 2016.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b). See 5 U.S.C. 601(2). Because the FCPIA Act mandates that this rulemaking be an interim final rule, FinCEN is not publishing a general notice of proposed rulemaking. Thus, the Regulatory Flexibility Act does not apply to this interim final rule.

V. Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 ("Unfunded Mandates Act") requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. FinCEN has determined that this interim final rule will not result in expenditures by state, local, and tribal governments, or by the private sector, of $100 million or more. Accordingly, FinCEN has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

VI. Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this is not a significant regulatory action for purposes of Executive Order 12866. Accordingly, a regulatory impact analysis is not required.

VII. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the interim final rule does not impose information collection requirements that would require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects in 31 CFR Part 1010

Authority delegations (Government agencies), Banks and banking, Currency, Investigations, Law enforcement, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, Part 1010 of Chapter X of title 31 of the Code of Federal Regulations is amended as follows:

PART 1010—GENERAL PROVISIONS

■ 1. The authority citation for part 1010 is revised to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314 and 5316–5332; title III, sec. 314, Pub. L. 107–56, 115 Stat. 307; sec. 701. Pub. L. 114–74, 129 Stat. 599.

■ 2. Amend § 1010.820 by adding paragraph (i) to read as follows:

§ 1010.820 Civil penalty.

* * * * *

(i) For penalties that are assessed after August 1, 2016, see § 1010.821 for rules relating to the maximum amount of the penalty.

■ 3. Add § 1010.821 to read as follows:

§ 1010.821 Penalty adjustment and table.

(a) *Inflation adjustments.* In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, ("FCPIA Act"), as further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, FinCEN has set forth in paragraph (b) of this section adjusted maximum penalty amounts for each civil monetary penalty provided by law within its jurisdiction that is subject to the FCPIA Act. The adjusted civil monetary penalty amounts replace the amounts published in the statutes authorizing the assessment of penalties.

(b) *Maximum civil monetary penalties.* The statutory penalty provisions and their adjusted maximum amounts or range of minimum and maximum amounts are set out in Table 1. The last column in the table provides the newly effective maximum penalty amounts or range of minimum and maximum amounts. These maximum penalty amounts do not, however, limit the total amount of a penalty in the case of a penalty that may be imposed for each day a violation continues.

TABLE 1 OF § 1010.821—PENALTY ADJUSTMENT AND TABLE

U.S. Code citation	Civil monetary penalty description	Statutory penalties as last amended by statute ($)	New maximum penalty amounts or range of minimum and maximum penalty amounts for penalties assessed after 8/1/2016 ($)
12 U.S.C. 1829b(j)	Relating to Recordkeeping Violations For Funds Transfers	10,000	19,787
12 U.S.C. 1955	Willful or Grossly Negligent Recordkeeping Violations	10,000	19,787
31 U.S.C. 5318(k)(3)(C)	Failure to Terminate Correspondent Relationship with Foreign Bank.	10,000	13,384
31 U.S.C. 5321(a)(1)	General Civil Penalty Provision for Willful Violations of Bank Secrecy Act Requirements.	25,000–$100,000	53,907–$215,628
31 U.S.C. 5321(a)(5)(B)(i).	Foreign Financial Agency Transaction—Non-Willful Violation of Transaction.	10,000	12,459
31 U.S.C. 5321(a)(5)(C)	Foreign Financial Agency Transaction—Willful Violation of Transaction.	100,000	124,588
31 U.S.C. 5321(a)(6)(A)	Negligent Violation by Financial Institution or Non-Financial Trade or Business.	500	1,078
31 U.S.C. 5321(a)(6)(B)	Pattern of Negligent Activity by Financial Institution or Non-Financial Trade or Business.	50,000	83,864
31 U.S.C. 5321(a)(7)	Violation of Certain Due Diligence Requirements, Prohibition on Correspondent Accounts for Shell Banks, and Special Measures.	1,000,000	1,338,420
31 U.S.C. 5330(e)	Civil Penalty for Failure to Register as Money Transmitting Business.	5,000	7,954

Dated: June 28, 2016.

Jamal El-Hindi,

Acting Director, Financial Crimes Enforcement Network.

[FR Doc. 2016–15653 Filed 6–29–16; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2016–0556]

Madison Regatta, Inc./Madison Regatta, Madison, IN

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulations.

SUMMARY: The Coast Guard will enforce special local regulations and a safety zone for the Madison Regatta for all waters of the Ohio River, beginning at mile marker 555.0 and ending at mile marker 560.0, Madison, IN. These actions are necessary to protect persons, property, and infrastructure from potential damage and safety hazards associated with a regatta taking place on the Ohio River. During the enforcement period, deviation from the regulations or safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Ohio Valley or a designated representative.

DATES: The regulations in 33 CFR 100.801, Table 1, Sector Ohio Valley, No. 16 and 33 CFR 165.801, Table 1, Sector Ohio Valley, No. 52 will be enforced from July 1 through July 3, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Petty Officer Caloeb Gandy, U.S. Coast Guard; telephone 502–779–5334, Email *Caloeb.l.gandy@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations listed in 33 CFR 100.801, Table 1, Sector Ohio Valley, No. 16, and the safety zone listed in 33 CFR 165.801, Table 1, Sector Ohio Valley, No. 52 during the Madison Regatta as follows:

July 1, 2016 from 8:00 a.m. to 6:00 p.m.
July 2, 2016 from 7:00 a.m. to 10:30 p.m.
July 3, 2016 from 7:00 a.m. to 6:30 p.m.

Under the provisions of 33 CFR part 100 and 33 CFR part 165, a vessel may not enter the regulated area, unless it receives permission from the COTP Ohio Valley or a designated representative. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter in, or impede the transit of race participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice of enforcement is issued under authority of 5 U.S.C. 552 (a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the enforcement periods for these regulations via the Local Notice to Mariners (LNM) and Broadcast Notice to Mariners (BNM).

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15506 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0280]

Drawbridge Operation Regulation; Chambers Creek, Steilacoom, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Chambers Creek Burlington Northern Santa Fe railroad vertical lift railroad bridge across Chambers Creek, mile 0.01, near

Steilacoom in Pierce County, WA. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is appropriate. This test deviation will modify the existing regulation to add an advance notification requirement for obtaining bridge openings during designated evening hours.

DATES: This deviation is effective from 12:01 on July 1, 2016 to 12:01 on December 27, 2016.

Comments and related material must reach the Coast Guard on or before November 22, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0280 using Federal eRulemaking Portal at *http://www.regulations.gov.*

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *Steven.M.Fischer3@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

The Chambers Creek Burlington Northern Santa Fe railroad vertical lift railroad bridge across Chambers Creek, mile 0.01, near Steilacoom in Pierce County, WA has a vertical clearance of 10ft in the closed to navigation position and 50ft of vertical clearance in the open to navigation position (reference plane is MHW elevation of 12.2 feet). The bridge currently operates under 33 CFR 117.5; which requires the bridge to open anytime when a request or signal to open is given.

The bridge owner, Burlington Northern Santa Fe Railroad, has observed minimal to no usage of the drawbridge between 10 p.m. and 6 a.m. and has requested to test this schedule to see if it better balances the needs of marine and rail traffic. The following facts support BNSF's proposal: (1) Over the last 6 years only 2% of the subject bridge lifts have occurred between the hours of 10 p.m. and 6 a.m., which equates to approximately 5 openings a year, (2) from February 2009 to June 2015 there were 1932 total openings of which only 40 occurred between the hours of 10 p.m. and 6 a.m., and (3) the navigation traffic consists primarily of the tenants of Chambers Bay marina (recreational users) that are members of the Chambers Bay Boating Association.

The Coast Guard is publishing this temporary deviation to test the proposed schedule change to determine whether a permanent change to the schedule is appropriate to better balance the needs of marine and rail traffic.

Under this temporary deviation, in effect from 12:01 on July 1, 2016 to 12:01 December 27, 2016, the subject bridge shall open on signal, except from 10 p.m. to 6 a.m. the draw shall open on signal if at least 4 hours notice is given. The bridge will be required to open as soon a possible, no later than 1 hour after notification, for vessels engaged in emergency response.

The Coast Guard will inform the users of the waterways of this temporary deviation through our Local and Broadcast Notices to Mariners and through direct outreach with the Chambers Creek Boating Association so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation. Vessels able to pass underneath the bridge in the closed position may do so at anytime.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

II. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this notice of temporary deviation, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

Dated: June 23, 2016.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2016–15439 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0473]

RIN 165–AA00

Safety Zones; Marine Events Held in the Sector Long Island Sound Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing four temporary safety zones for fireworks displays within the Coast Guard Sector Long Island Sound (LIS) Captain of the Port (COTP) Zone. This temporary final rule is necessary to provide for the safety of life on navigable waters during these events. Entry into, transit through, mooring or anchoring within these regulated areas is prohibited unless authorized by COTP Sector Long Island Sound.

DATES: This rule is effective without actual notice from June 30, 2016 through July 7, 2016. For the purposes of enforcement, actual notice will be used from the date the rule was signed, June 15, 2016, through June 30, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0473 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Petty Officer Jay TerVeen, Prevention Department, Coast Guard Sector Long Island Sound, telephone (203) 468–4446, email *Jay.C.TerVeen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
LIS	Long Island Sound
NPRM	Notice of Proposed Rulemaking
NAD 83	North American Datum 1983

II. Background Information and Regulatory History

This rulemaking establishes four safety zones for fireworks displays. Each event and its corresponding regulatory history are discussed below.

The Boys and Girls Club of Bellport-Beach Ball 2016 Fireworks Display is a recurring marine event with regulatory history. A safety zone was established for this event in 2015 via a temporary final rule entitled, "Safety Zones; Marine Events held in the Sector Long Island Sound Captain of the Port Zone." This rulemaking was published on May 18, 2015 in the **Federal Register** (80 FR 28176).

The Arts Project Cherry Grove Fireworks Display is a recurring marine event with regulatory history and is cited in 33 CFR 165.151, Table 1 to § 165.151, section 6.5. This event has been included in this rule due to deviation from the cite date.

The Salute to Veterans Fireworks Display is a recurring marine event with regulatory history and is cited in 33 CFR 165.151, Table 1 to § 165.151, section 6.4. This event has been included in this rule due to deviation from the cite date.

The Clinton Chamber of Commerce Fireworks Display is a recurring marine event with regulatory history. A safety zone was established for this event in 2015 via a temporary final rule entitled, "Safety Zones; Marine Events held in the Sector Long Island Sound Captain of the Port Zone." This rulemaking was published on August 14, 2015 in the **Federal Register** (80 FR 48692).

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM with respect to this rule because doing so would be impracticable. The event sponsors were late in submitting the marine event applications. These late submissions did not give the Coast Guard enough time to publish an NPRM, take public comments, and issue a final rule before these events take place. For that reason, issuing an NPRM would be impracticable.

Under 5 U.S.C. 553(d)(3), and for the same reasons stated in the preceding paragraph, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this temporary rule under authority in 33 U.S.C. 1231. The Captain of the Port (COTP) Long Island Sound has determined that the safety zones established by this temporary final rule are necessary to provide for the safety of life on navigable waterways before, during and after these scheduled events.

IV. Discussion of the Rule

This rule establishes four safety zones for four fireworks displays. The location of these safety zones are as follows:

FIREWORKS DISPLAYS SAFETY ZONES

1	Boys & Girls of Bellport-Beach Ball 2016	Location: All navigable waters of Patchogue Bay, Bellport, NY within 600 feet of the fireworks barge in approximate position 40°44′39.19″ N, 072°56′27.72″ W (NAD 83).
2	Arts Project Cherry Grove Fireworks Display	Location: All navigable waters of Great South Bay off Cherry Grove, Fire Island, NY within 600 feet of the fireworks barge in approximate position 40°39′49.06″ N, 073°05′27.99″ W (NAD 83).
3	The Salute to Veterans Fireworks Display	Location: All navigable waters of Reynolds Channel off Hempstead, NY 420 feet of the land launch in approximate position 40°35′36.62″ N, 073°35′20.72″ W (NAD 83).
4	Freeport Chamber of Commerce	Location: All navigable waters of Freeport Harbor, Freeport, NY within 300 feet of the fireworks barge located in approximate position 40°37′27.27″ N, 073°34′34.64″ W (NAD 83).

This rule prevents vessels from entering, transiting, mooring, or anchoring within the areas specifically designated as a safety zone and restricts vessel movement around the locations of the marine events to reduce the safety risks associated with it during the period of enforcement unless authorized by the COTP or designated representative.

The Coast Guard will notify the public and local mariners of these safety zones through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes and Executive order and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The Coast Guard determined that this rulemaking is not a significant regulatory action for the following reasons: (1) The enforcement of these safety zones will be relatively short in duration; (2) persons or vessels desiring to enter these safety zones may do so with permission from the COTP LIS or a designated representative; (3) these safety zones are designed in a way to limit impacts on vessel traffic, permitting vessels to navigate in other portions of the waterway not designated as a safety zone; and (4) the Coast Guard will notify the public of the enforcement of this rule via appropriate means, such as via Local Notice to Mariners and Broadcast Notice to Mariners to increase public awareness of this safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit these regulated areas may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator. Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Orders 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This temporary rule involves the establishment of four temporary safety zones. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination will be available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and Department of Homeland Security Delegation No. 0170.1

■ 2. Add § 100.T01–0473 to read as follows:

§ 165.T01–0473 Safety Zones; Marine Events held in the Sector Long Island Sound Captain of the Port Zone.

(a) *Location.* This section will be enforced at the locations listed for each event in Table 1 to § 165.T01–0473.

(b) *Enforcement period.* This rule will be enforced on the dates and times listed for each event in Table 1 to § 165.T01–0473.

(c) *Definitions.* The following definitions apply to this section: A "designated representative" is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the COTP, Sector Long Island Sound, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. "Official patrol vessels" may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP Sector Long Island Sound. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(d) *Regulations.* (1) The general regulations contained in § 165.23 apply.

(2) In accordance with the general regulations in § 165.23, entry into or

movement within these zones are prohibited unless authorized by the COTP, Long Island Sound.

(3) Any vessel given permission to deviate from these regulations must comply with all directions given to them by the COTP Sector Long Island Sound, or the designated on-scene representative.

(4) Any vessel given permission to enter or operate in these safety zones must comply with all directions given to them by the COTP Sector Long Island Sound, or the designated on-scene representative.

(5) Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

TABLE 1 TO § 165.T01–0473

Fireworks Events	
1. Boys & Girls of Bellport-Beach Ball 2016	• Date: June 18, 2016 • Rain Date: June 19, 2016 • Time: 8:30 p.m. to 10:00 p.m. • Location: All navigable waters of Patchogue Bay, Bellport, NY within 600 feet of the fireworks barge in approximate position 40°44′39.19″ N, 072°56′27.72″ W (NAD 83).
2. Arts Project Cherry Grove Fireworks Display	• Date: June 18, 2016 • Rain Date: June 19, 2016 • Time: 8:50 p.m. to 10:00 p.m. • Location: All navigable waters of Great South Bay off Cherry Grove, Fire Island, NY within 600 feet of the fireworks barge in approximate position 40°39′49.06″ N, 073°05′27.99″ W (NAD 83).
3. The Salute to Veterans Fireworks Display	• Date: June 25, 2016 • Rain Date: June 26, 2016 • Time: 9:00 p.m. to 10:30 p.m. • Location: All navigable waters of Reynolds Channel off Hempstead, NY within 420 feet of the land launch in approximate position 40°35′36.62″ N, 073°35′20.72″ W (NAD 83).
4. Freeport Chamber of Commerce	• Date: June 30, 2016 • Rain Date: July 7, 2016 • Time: 7:45 p.m. to 10:00 p.m. • Location: All navigable waters of Freeport Harbor, Freeport, NY within 300 feet of the fireworks barge located in approximate position 40°37′27.27″ N, 073°34′34.64″ W (NAD 83).

Dated: June 15, 2016.

E.J. Cubanski, III,

Captain, U.S. Coast Guard, Captain of the Port Sector Long Island Sound.

[FR Doc. 2016–15601 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0526]

Safety Zones; Recurring Events in Captain of the Port Boston Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce safety zones in the Captain of the Port Boston Zone on the specified dates and times listed below. This action is necessary to ensure the protection of the maritime public and event participants from the hazards associated with these annual recurring events. Under the provisions of our regulations, no person or vessel, except for the safety vessels assisting with the event may enter the safety zones unless given permission from the COTP or the designated on-scene representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

DATES: The regulations in 33 CFR 165.118 will be enforced for the safety zones identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Mr. Mark Cutter, Coast Guard Sector Boston Waterways Management Division, telephone 617–223–4000, email *Mark.E.Cutter@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones listed in 33 CFR 165.118 on the specified dates and times as indicated in Table 1 below. This regulation was published in the **Federal Register** on November 8, 2013 (78 FR 67028).

TABLE 1

7.1 City of Lynn 4th of July Celebration Fireworks	• Event Type: Firework Display. • Sponsor: City of Lynn. • Date: July 3, 2016. • Time: 7:00 p.m. to 10:00 p.m. • Location: All waters of Nahant Bay, within a 350-yard radius of the fireworks barge located at position 42°27.51′ N., 070°55.52′ W. (NAD 83).
7.2 Gloucester July 4th Celebration Fireworks	• Event Type: Fireworks Display. • Sponsor: The Gloucester Fund. • Date: July 3, 2016. • Time: 8:00 p.m. to 11:00 p.m.

TABLE 1—Continued

	• Location: All waters of Gloucester Harbor, Stage Fort Park, within a 350-yard radius of the fireworks launch site on the beach located at position 42°36.3′ N., 070°40.5′ W. (NAD 83).
7.3 Manchester by the Sea Fireworks	• Event Type: Fireworks Display. • Sponsor: Manchester Parks and Recreation Department. • Date: July 4, 2016. • Time: 9:00 p.m. to 10:00 p.m. • Location: All waters of Manchester Bay within a 350-yard radius of the fireworks launch site barge located at position 42°34.14′ N., 070°45.53′ W. (NAD 83).
7.4 Weymouth 4th of July Celebration Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Weymouth 4th of July Committee. • Date: July 3, 2016. • Time: 8:30 p.m. to 11:30 p.m. • Location: All waters of Weymouth Fore River, within a 350-yard radius of the fireworks launch site located at position 42°15.5′ N., 070°56.1′ W. (NAD 83).
7.5 Beverly 4th of July Celebration Fireworks	• Event Type: Fireworks Display. • Sponsor: Beverly Harbormaster. • Date: July 4, 2016. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of Beverly Harbor within a 350-yard radius of the fireworks launch barge located at position 42°33.46′ N., 070°48.28′ W. (NAD 83).
7.6 4th of July Celebration Fireworks	• Event Type: Fireworks Display. • Sponsor: Prides Crossing 4th of July Committee. • Date: July 4, 2016. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of Manchester Bay within a 350-yard radius of the fireworks launch site near West Beach located at position 42°33.46′ N., 070°48.28′ W. (NAD 83).
7.7 Boston Pops Fireworks	• Event Type: Fireworks Display. • Sponsor: Boston 4 Celebrations. • Date: July 4, 2016. • Time: 8:30 p.m. to 11:00 p.m. • Location: All waters of the Charles River within a 350-yard radius of the fireworks barges located in the vicinity of position 42°21.24′ N., 071°04.60′ W. (NAD 83).
7.8 City of Salem Fireworks	• Event Type: Fireworks Display. • Sponsor: City of Salem. • Date: July 4, 2016. • Time: 9:15 p.m. to 10:15 p.m. • Location: All waters of Salem Harbor, within a 350-yard radius of the fireworks launch site located on Derby Wharf at position 42°31.15′ N., 070°53.13′ W. (NAD 83).
7.9 Marblehead 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Marblehead. • Date: July 4, 2016. • Time: 9:30 p.m. to 10:00 p.m. • Location: All waters of Marblehead Harbor within a 350-yard radius of the fireworks launch site located at position 42°30.34′ N., 070°50.13′ W. (NAD 83).
7.10 Plymouth 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: July 4 Plymouth, Inc. • Date: July 4, 2016. • Time: 9:00 p.m. to 10:00 p.m. • Location: All waters of Plymouth Harbor within a 350-yard radius of the fireworks launch site located at position 42°57.3′ N., 070°38.3′ W. (NAD 83).
7.11 Town of Nahant Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Nahant. • Date: July 4, 2016. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of Nahant Harbor within a 350-yard radius of the fireworks launch site on Bailey's Hill Park located at position 42°25.1′ N., 070°55.8′ W. (NAD 83).
7.13 Yankee Homecoming Fireworks	• Event Type: Fireworks Display. • Sponsor: Yankee Homecoming. • Date: August 6, 2016. • Time: 9:00 p.m. to 10:00 p.m. • Location: All waters of the Merrimack River, within a 350-yard radius of the fireworks launch site located at position 42°48.97′ N., 070°52.68′ W. (NAD 83).
7.14 Hingham 4th of July Fireworks	• Event Type: Fireworks Display.

TABLE 1—Continued

	• Sponsor: Hingham Lions Club. • Date: July 2, 2016. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters within a 350-yard radius of the beach on Button Island located at position 42°15.07′ N., 070°53.03′ W. (NAD 83).
7.17 Salisbury 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Salisbury Chamber of Commerce. • Date: July 4, 2016. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of the Atlantic Ocean near Salisbury Beach within a 350-yard radius of the fireworks launch site located at position 42°50.6′ N., 070°48.4′ W. (NAD 83).
7.19 Swim Across America Boston	• Event Type: Swim. • Sponsor: Swim Across America. • Date: July 8, 2016. • Time: 6:00 a.m. to 4:00 p.m. • Location: All waters of Boston Harbor between Rowes Warf and Little Brewster Island within the following points (NAD 83): 42°21.4′ N., 071°03.0′ W. 42°21.5′ N., 071°02.9′ W. 42°19.8′ N., 070°53.6′ W. 42°19.6′ N., 070°53.4′ W.

This notice of enforcement is issued under authority of 33 CFR 165.118 and 5 U.S.C. 552 (a). In addition to this notice of enforement in the **Federal Register**, the Coast Guard will provide notification of these enforcement periods via the Local Notice to Mariners and Broadcast Notice to Mariners.

Dated: June 23, 2016.

C.C. Gelzer,

Captain, U.S. Coast Guard, Captain of the Port Boston.

[FR Doc. 2016–15501 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0456]

Safety Zone; City of Charleston Independence Celebration, Charleston, WV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce safety zone for the City of Charleston Independence Celebration Fireworks on the Kanawha River from mile marker 58.1 to mile marker 59.1, in Charleston, WV on July 3, 2016. This action is needed to provide for the safety of life on navigable waterways during a fireworks display on or over the waterway. Our regulation for Recurring Marine Events in Captain of the Port Ohio Valley Zone identifies the safety zone for this fireworks display. During the enforcement period, no vessel may transit this regulated area without approval from the Captain of the Port or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, Sector Ohio Valley, No. 31 will be enforced from 9:15 p.m. until 10:15 p.m. on July 3, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST3 Robert Miller, Marine Safety Unit Huntington, U.S. Coast Guard; telephone 304–733–0198, *Robert.A.Miller2@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone for the annual City of Charleston Independence Celebration Fireworks listed in 33 CFR 165.801, Table 1, Sector Ohio Valley, No. 31, from 9:15 p.m. until 10:15 p.m. on July 3, 2016. This safety zone extends from mile marker 58.1 to mile marker 59.1 on the Kanawha River in Charleston, WV. This action is being taken to provide for the safety of life on navigable waterways during the fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative. Persons or vessels desiring to enter into or passage through the zone must request permission from the Captain of the Port Ohio Valley or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the Captain of the Port Ohio Valley or designated representative.

This notice of enforcement is issued under authority of 33 CFR 165.801 and 5 U.S.C. 552 (a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and updates via marine information broadcasts on channel 16.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15505 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0340]

RIN 1625–AA00

Safety Zones; Safety Zones Within the Captain of the Port New Orleans Zone; New Orleans to Baton Rouge, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones for multiple locations and dates within the Captain of the Port New Orleans zone. These safety zones are necessary to protect persons and vessels from potential safety hazards associated with fireworks displays on or over federal waterways. Entry into these zones is prohibited unless specifically authorized by the Captain of the Port New Orleans or a designated representative.

DATES: This rule is effective without actual notice from June 30, 2016 through September 23, 2016. For the purposes of enforcement, actual notice will be used from June 22, 2016 through June 30, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0340 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this temporary final rule, call or email Lieutenant Commander (LCDR) Howard Vacco, Sector New Orleans, at (504) 365–2281 or *Howard.K.Vacco@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

BNM	Broadcast Notice to Mariners
CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
MSIB	Marine Safety Information Bulletin
TFR	Temporary Final Rule
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard was notified about several fireworks displays, occurring between June 22 and September 23, 2016 as follows:

(1) The U.S. Travel Association's "IPW" Conference scheduled for one hour in the evening between 6:00 p.m. and 11:00 p.m. on June 22, 2016. The fireworks barge will be positioned adjacent to Mardi Gras World in New Orleans, LA, at approximate mile marker 96.2 above Head of Passes on the Lower Mississippi River. The Coast Guard was notified about this event on April 1, 2016.

(2) The St. John the Baptist Parish Independence Day Celebration scheduled for one hour in the evening between 6:00 p.m. and 11:00 p.m. on June 30, 2016. The fireworks barge will be positioned adjacent to the Parish Courthouse in Edgard, LA, at approximate mile marker 138.0 above Head of Passes on the Lower Mississippi River. The Coast Guard was notified about this event on March 15, 2016. This is an annually recurring event that is published in 33 CFR 165.801, Table 5, line no. 2. This year's occurrence is scheduled for a different date and location than currently listed in the CFR.

(3) The L'Auberge Casino Independence Day Celebration scheduled for one hour in the evening between 6:00 p.m. and 11:00 p.m. on July 4, 2016. The fireworks barge will be positioned adjacent to the L'Auberge Casino in Baton Rouge, LA, at approximate mile marker 216.5 above Head of Passes on the Lower Mississippi River. The Coast Guard was notified about this event on January 27, 2016.

(4) The City of Mandeville Independence Day Celebration scheduled for one hour in the evening between 6:00 p.m. and 11:00 p.m. on July 4, 2016. The fireworks barge will be positioned adjacent to the Mandeville City Lakefront in Mandeville, LA, at approximate position 30° 21.200 N., 90° 04.500 W. The Coast Guard was notified about this event on March 14, 2016.

(5) The American Pyrotechnic Association Convention scheduled for one hour in the evening between 6:00 p.m. and 11:00 p.m. on September 23, 2016. The fireworks barge will be positioned adjacent to Dumaine Street in New Orleans, LA, at approximate mile marker 94.5 above Head of Passes on the Lower Mississippi River. The Coast Guard was notified about this event on February 24, 2016. This event was incorrectly identified as "The American Psychological Association Convention" in the NPRM.

Due to the risks associated with aerial barge-based fireworks displays taking place on and over these sections of navigable waterways, the safety zones are needed to protect persons and property. The Coast Guard will notify the public and maritime community of the safety zones and their respective enforcement periods via broadcast notices to mariners (BNM) and Marine Safety Information Bulletins (MSIB).

In response, on June 3, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zones; Safety Zones Within the Captain of the Port New Orleans Zone; New Orleans to Baton Rouge, LA (81 FR 35671). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to these fireworks displays. During the comment period that ended June 20, 2016, we received no comments.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Due to the risks associated with aerial barge-based fireworks displays taking place on and over the waterway, safety zones are needed. The Coast Guard finds that good cause exists for not waiting 30 days after publication in the **Federal Register**. Providing a full 30-days notice would be impracticable because immediate action is needed beginning June 22, 2016 to protect persons and property from the hazards associated with an aerial fireworks display taking place on and over the waterway.

The Coast Guard will notify the public and maritime community that the safety zone will be in effect and of its enforcement periods via broadcast notices to mariners (BNM).

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port New Orleans (COTP) has determined that potential hazards associated with the fireworks to be used in upcoming displays will be a safety concern for anyone within one-quarter mile of the fireworks barge for the displays on the Lower Mississippi River and within 600 feet of the fireworks barge for the display in Lake Pontchartrain. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled events.

IV. Discussion of Comments, Changes, and the Rule

Through this temporary final rule, the Coast Guard is establishing multiple temporary safety zones within the Captain of the Port New Orleans (COTP) Zone on several different dates and in several different locations. While we received no comments to the proposed rule, due to timing of the NPRM publication and cancellation of an event, 2 safety zones are removed and changes to the proposed rule are necessary. We removed the regulatory text for the first safety zone, under paragraph (a)(1) as proposed, which was for a fireworks display on June 15, 2016, from MM 94.0 to MM 95.0 above head of passes on the Lower Mississippi River. We removed the regulatory text for that safety zone because we established it through its own temporary rulemaking before the comment period for the NPRM ended. This allowed the Coast Guard to ensure that the necessary safety measures were in place for the June 15, 2016 display. A copy of that rule is available in the docket as indicated under **ADDRESSES**. We also removed the regulatory text for the second safety zone, under paragraph (a)(2) because that event was cancelled and the safety zone no longer needed. Accordingly, paragraphs (a)(3) through (7) of the proposed rule are renumbered in this temporary final rule as paragraphs (a)(1) through (5), with the same regulatory text as proposed in the NPRM.

These remaining safety zones will be enforced on the respective dates listed above and in the regulatory text as provided at the end of this document.

Each safety zone will occur during the evening on the dates specified, and will be limited to a duration of one hour, between the hours of 6:00 p.m. and 11:00 p.m. Entry into these safety zones is prohibited unless permission has been granted by the COTP New Orleans, or a designated representative.

The COTP New Orleans will inform the public through BNMs of the enforcement period for each safety zone as well as any changes in the planned schedule. Mariners and other members of the public may also contact Coast Guard Sector New Orleans Command Center to inquire about the status of the safety zone by calling (504) 365–2200.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

Four of these safety zones are no greater than 1 river mile in length and would restrict navigation on the Lower Mississippi River for no longer than one hour. The remaining safety zone is limited to a circular area 1200 feet in diameter located along the North Shore of Lake Pontchartrain, in an area with ample room for other traffic to navigate around the safety zone, and would be in effect for no longer than one hour. Due to the limited scope and short duration of each safety zone, the impacts on routine navigation are expected to be minimal. Additionally, the Coast Guard will issue maritime notices widely available to waterway users and deviation from the safety zones may be requested and will be considered on a case-by-case basis.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule establishes five temporary safety zones within the Captain of the Port New Orleans zone. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES.** We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER**

INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0340 to read as follows:

§ 165.T08–0340 Safety Zones; Captain of the Port New Orleans Zone; New Orleans to Baton Rouge, LA.

(a) *Safety zones.* The following areas are safety zones:

(1) *U.S. Travel Association fireworks display, New Orleans, LA*—(i) *Location.* All waters of the Lower Mississippi River from mile marker 95.7 to mile marker 96.7 Above Head of Passes.

(ii) *Effective date and time.* June 22, 2016, for one hour in the evening between the hours of 6:00 p.m. and 11:00 p.m.

(2) *St. John the Baptist Independence Day Celebration fireworks display, Edgard, LA*—(i) *Location.* All waters of the Lower Mississippi River from mile marker 137.5 to mile marker 138.5 Above Head of Passes.

(ii) *Effective date and time.* June 30, 2016, for one hour in the evening between the hours of 6:00 p.m. and 11:00 p.m.

(3) *L'Auberge Casino Independence Day Celebration fireworks display, Baton Rouge, LA*—(i) *Location.* All waters of the Lower Mississippi River from mile marker 216.0 to mile 217.0 Above Head of Passes.

(ii) *Effective date and time.* July 4, 2016, for one hour in the evening between the hours of 6:00 p.m. and 11:00 p.m.

(4) *City of Mandeville Independence Day Celebration fireworks display, Mandeville, LA*—(i) *Location.* All waters of Lake Pontchartrain extending 600 feet in any direction from 30° 21.200 N., 090° 04.500 W.

(ii) *Effective date and time.* July 4, 2016, for one hour in the evening between the hours of 6:00 p.m. and 11:00 p.m.

(5) *American Pyrotechnic Association Convention fireworks display, New Orleans, LA*—(i) *Location.* All waters of the Lower Mississippi River from mile marker 94.0 to mile marker 95.0 Above Head of Passes.

(ii) *Effective date and time.* September 23, 2016, for one hour in the evening between the hours of 6:00 p.m. and 11:00 p.m.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into these zones is prohibited unless specifically authorized by the Captain of the Port (COTP) New Orleans or designated personnel. Designated personnel include Commissioned, Warrant and Petty Officers of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans. For each event, the COTP New Orleans Designated Representative will be announced via Marine Safety Information Bulletin and Notice to Mariners.

(2) Vessels requiring deviation from this rule must request permission from the COTP New Orleans or a COTP New Orleans designated representative. They may be contacted via the U.S. Coast Guard Sector New Orleans Command Center, via VHF–FM Channel 16 or by phone at (504) 365–2200.

(3) Persons and vessels permitted to deviate from this safety zone regulation and enter the restricted areas must transit at the slowest safe speed and comply with all lawful directions issued by the COTP New Orleans or the designated representative.

(c) *Information broadcasts.* The COTP New Orleans or designated representative will inform the public through broadcast notices to mariners of the enforcement periods for the safety zones as well as any changes in the planned schedules.

Dated: June 22, 2016.

P.C. Schifflin,

Captain, U.S. Coast Guard, Captain of the Port New Orleans.

[FR Doc. 2016–15440 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0481]

RIN 1625–AA00

Safety Zone; City of Bayfield Fourth of July Fireworks, Lake Superior, Bayfield, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in Lake Superior near Bayfield, WI. This safety zone is intended to restrict vessels from specified waters in Lake Superior during the Bayfield Fourth of July Fireworks Display. This safety zone is necessary to protect spectators from the hazards associated with the fireworks display.

DATES: This rule is effective from 9 p.m. through 11 p.m. July 4, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type USCG–2016–0481 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade John Mack, Waterways management, MSU Duluth, Coast Guard; telephone 218–725–3818, email *John.V.Mack@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. Because the event is scheduled for July 4, 2016, there is insufficient time to accommodate the comment period. Thus, delaying the effective date of this rule to wait for the comment period to run would be both impracticable and contrary to public interest because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with the event.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest as it would inhibit the Coast Guard's ability to protect spectator and vessels from the hazards associated with the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with fireworks displays starting at 9:30 p.m. on July 4, 2016 will be a safety concern for anyone within a 420-foot radius of the launch site. The likely combination of recreational vessels, darkness punctuated by bright flashes of light, and fireworks debris falling into the water presents risks of collisions which could result in serious injuries or fatalities. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 9 p.m. through 11 p.m. July 4, 2016. The safety zone will cover all navigable waters within an area bounded by a circle with a 420-foot radius of the fireworks display launching site located in Hancock, MI at coordinates 46°48′40″ N., 090°48′32″ W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive order related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Keweenaw Waterway in Hancock, MI for 1 hour and during a time of year when commercial vessel traffic is normally low. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of

$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting no more than 2 hours that will prohibit entry within a 420-foot radius from where a fireworks display will be conducted. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0481 to read as follows:

§ 165.T09–0481 Safety Zone; City of Bayfield Fourth of July Fireworks, Lake Superior, Bayfield, WI.

(a) *Location.* All waters of Lake Superior within an area bounded by a circle with a 420-foot radius at position 46°48′40″ N., 090°48′32″ W.

(b) *Effective period.* This safety zone is effective from 9 p.m. through 11 p.m. on July 4, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Duluth, or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Duluth or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Duluth or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Duluth or his on-scene representative.

Dated: June 24, 2016.

A.H. Moore, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2016–15438 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0478]

Safety Zones; Duluth Fourth Fest, Duluth, MN

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Safety Zone for the Duluth Fourth Fest fireworks display in Duluth, MN July 4, 2016. This action is necessary to protect spectators during the Duluth Fourth Fest Fireworks show. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative.

DATES: The regulations in 33 CFR 165.943(b) will be enforced from 9:30 p.m. through 11:30 p.m. on July 4, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Junior Grade John Mack, Waterways Management Division, Coast Guard; telephone (218) 725–3818, email *John.V.Mack@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone for the annual Duluth Fourth Fest fireworks display in 33 CFR 165.943(a)(3) from 9:30 p.m. until 11:30 p.m. July 4, 2016. This safety zone will include all U.S. navigable waters of the Duluth Harbor Basin Northern Section within a 840 foot radius of position 46°46′14″ N., 092°06′16″ W. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative. The Captain of the Port's designated on-scene representative may be contacted via VHF Channel 16.

This notice of enforcement is issued under authority of 33 CFR 165.943 and 5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of the enforcement of this safety zone via Broadcast Notice to Mariners.

Dated: June 24, 2016.

A.H. Moore, Jr.,

Commander, U.S. Coast Guard, Captain of the Port, Duluth.

[FR Doc. 2016–15503 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0289]

RIN 1625–AA00

Safety Zone, Pamlico Sound; Ocracoke, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the Pamlico Sound in Ocracoke, North Carolina within a 500 yard radius of the National Park Service (NPS) Boat Launch. This action is necessary to provide the safety of mariners on navigable waters to protect the life and property of the maritime public and spectators from the hazards posed by Hyde County 4th of July aerial fireworks display. Entry into or movement within the safety zone during the enforcement period is prohibited without approval of the Captain of the Port.

DATES: This rule is effective on July 3, 2016, from 9 p.m. through 9:45 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type USCG–2016–0289 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Derek J. Burrill, Waterways Management Division Chief, Sector North Carolina, Coast Guard; telephone (910) 772–2230, email *Derek.J.Burrill@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard was awaiting further details on the location of the launch site and also gathering other safety details of the Hyde County July 4th Fireworks display. The Captain of the Port North Carolina is establishing a temporary safety zone on specified waters of Pamlico Sound within a 500 yard radius of the NPS Boat Launch in approximate position 35°07′07″ N., longitude 075°59′16″ W. (NAD 1983) in Ocracoke, NC. This safety zone will be effective and enforced from 9 p.m. to 9:45 p.m. on July 3, 2016. It is impracticable to publish a Notice to Public Rulemaking (NPRM) because we must establish this safety zone by July 3, 2016, and sufficient notice was not given to publish a NPRM due to the Coast Guard awaiting further details on the location of the launch site and continuing to gather other on site safety details associated with the aerial fireworks display.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to public interest because the potential hazards creating the need for this rule will occur during the aerial fireworks display scheduled for July 3, 2016.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port North Carolina (COTP) has determined that potential hazards associated with the aerial fireworks on July 3, 2016, will be a safety concern for anyone within a 500 yard radius of the launch site at approximate position 35°07′07″ N., longitude 075°59′16″ W. (NAD 1983). This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

IV. Discussion of the Rule

This rule establishes a safety zone from 9 p.m. to 9:45 p.m. on July 3, 2016. The safety zone will cover all navigable waters within 500 yards of the NPS Boat Launch at approximate position 35°07′07″ N., longitude 075°59′16″ W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the aerial fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The primary impact of these regulations will be on limiting all vessels wishing to transit the affected waterways during enforcement of the safety zone on the waters of Pamlico Sound within a 500 yard radius of the NPS Boat Launch at approximate position 35°07′07″ N., longitude 075°59′16″ W. on July 3, 2016, from 9 p.m. through 9:45 p.m., unless otherwise cancelled by the COTP. Although these regulations prevent traffic from transiting a small portion of Pamlico Sound during this event, that restriction is limited in duration, affects only a limited area, and will be well publicized to allow mariners to make alternative plans for transiting the affected area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone to limit all vessels within a 500 yard radius of the NPS Boat Launch at approximate position 35°07′07″ N., longitude 075°59′16″ W. on July 3, 2016, from 9 p.m. through 9:45 p.m., to protect life and property of mariners from the dangers associated with aerial fireworks. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165— REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0289 to read as follows:

§ 165.T05–0289 Safety Zone, Pamlico Sound; Ocracoke, North Carolina.

(a) *Definitions.* For the purposes of this section:

Captain of the Port means the Commander, Sector North Carolina.

Representative means any Coast Guard commissioned, warrant or petty officer who has been authorized to act on the behalf of the Captain of the Port.

(b) *Location.* The following area is a safety zone: specified waters of the Captain of the Port Sector North Carolina zone, as defined in 33 CFR 3.25–10, all waters of Pamlico Sound in Ocracoke, NC within a 500-foot radius of the NPS Boat Launch in Ocracoke, NC at approximate position 35°07′07″ N., longitude 075°59′16″ W.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless authorized by the Captain of the Port, North Carolina or her designated representatives.

(2) The operator of any vessel granted permission to enter this safety zone must proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, North Carolina can be reached through the Sector North Carolina Command Duty Officer at Sector North Carolina in Wilmington, North Carolina at telephone number (910) 343–3882.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65 Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement period.* This section will be enforced on July 3, 2016, from 9 p.m. through 9:45 p.m., unless otherwise cancelled by the COTP.

Dated: June 9, 2016.

P.J. Hill,

Captain, U.S. Coast Guard, Captain of the Port North Carolina.

[FR Doc. 2016–15600 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0614]

RIN 1625–AA00

Safety Zone; Fireworks Display; Ohio River Mile 469.6 to 470.2, Newport, KY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Ohio River, surface to bottom, from mile 469.6 to 470.2. This action is necessary to provide for the safety of life on these navigable waters near Newport, KY, during the City of Newport Fireworks Display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Ohio Valley (COTP) or a designated representative.

DATES: This rule is effective from 10:00 p.m. to 11:00 p.m. on July 3, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0614 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Petty Officer Caloeb Gandy, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5334, email *Caloeb.l.gandy@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor submitted the event application on June 22, 2016. This late submission did not give the Coast Guard enough time to complete the full NPRM process. This action is necessary to ensure the safety of the life and property during the fireworks display on or over this navigable waterway. It is impracticable to publish an NPRM because we must establish this safety zone by July 3, 2016.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during the event and immediate action is necessary to prevent possible loss of life and property.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Ohio Valley (COTP) has determined that potential hazards associated with the fireworks display on July 3, 2016 will be a safety concern for all waters of the Ohio River, surface to bottom, from mile 469.6 to 470.2. The purpose of this rule is to ensure safety of life on the navigable waters in the temporary safety zone before, during, and after the City of Newport Fireworks Display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on July 3, 2016. The temporary safety zone will cover all waters of the Ohio River, surface to bottom, from mile 469.6 to 470.2. Transit into and through this area is prohibited from 10:00 p.m. to 11:00 p.m. on July 3, 2016. The duration of the temporary safety zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks displays. No vessel or person will be permitted to enter the temporary safety zone without obtaining permission from the COTP or a designated representative. Deviation requests will be considered and reviewed on a case-by-case basis. The COTP Ohio Valley may be contacted by telephone at 1–800–253–7475 or can be reached by VHF–FM channel 16. Public notifications will be made to the local maritime community prior to the event through the Local Notice to Mariners, and Broadcast notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-year of the temporary safety zone. The temporary safety zone will only be in effect for 60 minutes, during late evening hours and covers an area of the waterway stretching less than one mile. The Coast Guard expects minimum adverse impact to mariners from the temporary safety zone activation as the event has been advertised to the public. Also, mariners may request authorization from the COTP Ohio Valley or a designated representative to transit the temporary safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $165,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone lasting less than two hours that will prohibit entry on all waters of the Ohio River, surface to bottom, extending 500 feet from the Kentucky shoreline, from mile 469.6 to 470.2. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES.**

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0614 to read as follows:

§ 165.T08–0614 Safety Zone; Ohio River Between Mile 469.6 and 470.2, Newport, KY.

(a) *Location.* The following area is a temporary safety zone for all waters, surface to bottom, of the Ohio River between mile 469.6 and mile 470.2, Newport, KY.

(b) *Enforcement period.* This temporary safety zone will be enforced from 10:00 p.m. to 11:00 p.m. on July 3, 2016. Actual notice will be used for enforcement purposes.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley (COTP) or designated personnel. Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

(2) Persons and vessels permitted to deviate from this safety zone regulation and enter the restricted area must transit at the slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative.

(d) *Informational broadcasts.* The COTP Ohio Valley or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the temporary safety zone as well as any changes in the planned schedule.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15507 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0596]

RIN 1625–AA00

Safety Zone; Fireworks Display; Ohio River Mile 408 to 409, Maysville, KY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for

all waters of the Ohio River, surface to bottom, extending 500 feet from the Kentucky shoreline, from mile 408 to 409. This action is necessary to provide for the safety of life on these navigable waters near Maysville, KY, during the City of Maysville Fireworks Display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Ohio Valley (COTP) or a designated representative.

DATES: This rule is effective from 10:00 p.m. to 11:00 p.m. on July 4, 2016

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0596 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Petty Officer Caloeb Gandy, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5334, email *Caloeb.l.gandy@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor submitted the event application on May 11, 2016. This late submission did not give the Coast Guard enough time to complete the full NPRM process. This action is necessary to ensure the safety of the life and property during the fireworks display on or over this navigable waterway. It is impracticable to publish an NPRM because we must establish this safety zone by July 4, 2016.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during the event and immediate action is necessary to prevent possible loss of life and property.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Ohio Valley (COTP) has determined that potential hazards associated with the fireworks display on July 4, 2016 will be a safety concern for all waters of the Ohio River, surface to bottom, extending 500 feet from the Kentucky shoreline, from mile 408 to 409. The purpose of this rule is to ensure safety of life on the navigable waters in the temporary safety zone before, during, and after the City of Maysville Fireworks Display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on July 4, 2016. The temporary safety zone will cover all waters of the Ohio River, surface to bottom, extending 500 feet from the Kentucky shoreline, from mile 408 to 409. Transit into and through this area is prohibited from 10:00 p.m. to 11:00 p.m. on July 4, 2016. The duration of the temporary safety zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks displays. No vessel or person will be permitted to enter the temporary safety zone without obtaining permission from the COTP or a designated representative. Deviation requests will be considered and reviewed on a case-by-case basis. The COTP Ohio Valley may be contacted by telephone at 1–800–253–7475 or can be reached by VHF–FM channel 16. Public notifications will be made to the local maritime community prior to the event through the Local Notice to Mariners, and Broadcast notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-year of the temporary safety zone. The temporary safety zone will only be in effect for 60 minutes and covers an area of the waterway stretching less than one mile and extending 500 feet from the shoreline. The Coast Guard expects minimum adverse impact to mariners from the temporary safety zone activation as the event has been advertised to the public. Also, mariners may request authorization from the COTP Ohio Valley or a designated representative to transit the temporary safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $165,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone lasting less than two hours that will prohibit entry on all waters of the Ohio River, surface to bottom, extending 500 feet from the Kentucky shoreline, from mile 408 to 409. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0596 to read as follows:

§ 165.T08–0596 Safety Zone; Ohio River Between Mile 408 and 409, Maysville, KY.

(a) *Location.* The following area is a temporary safety zone for all waters, surface to bottom, of the Ohio River between mile 408 and mile 409, Maysville, KY, extending 500 feet from the Kentucky shoreline.

(b) *Enforcement period.* This temporary safety zone will be enforced from 10:00 p.m. to 11:00 p.m. on July 4, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley (COTP) or designated personnel. Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

(2) Persons and vessels permitted to deviate from this safety zone regulation and enter the restricted area must transit at the slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Informational broadcasts.* The COTP Ohio Valley or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the temporary safety zone as well as any changes in the planned schedule.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15504 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0479]

Safety Zones; Superior Man Triathlon, Duluth, MN

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Safety Zone for the Superior Man Triathlon in Duluth, MN August 28, 2016. This action is necessary to protect the participants during the event. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative.

DATES: The regulations in 33 CFR 165.943(b) will be enforced from 5:30 a.m. through 9:30 a.m. on August 28, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Junior Grade John Mack, Waterways

Management Division, Coast Guard; telephone (218) 725–3818, email *John.V.Mack@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone for the annual Superior Man Triathlon in Duluth, MN in 33 CFR 165.943(a)(8) from 5:30 a.m. until 9:30 a.m. August 28, 2016. This safety zone will include all U.S. navigable waters of the Duluth Harbor Basin, Northern Section within an imaginary line beginning at point 46°46′36.12″ N. 092°06′06.99″ W., running southeast to 46°46′32.75″ N. 092°06′01.74″ W., running northeast to 46°46′45.92″ N. 092°05′45.18″ W., running northwest to 46°46′49.47″ N. 092°05′49.35″ W. and finally running southwest back to the starting point. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative. The Captain of the Port's designated on-scene representative may be contacted via VHF Channel 16.

This notice of enforcement is issued under authority of 33 CFR 165.943 and 5 U.S.C. 552 (a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of the enforcement of this safety zone via Broadcast Notice to Mariners.

Dated: June 24, 2016.

A.H. Moore, Jr.,

Commander, U.S. Coast Guard, Captain of the Port, Duluth.

[FR Doc. 2016–15502 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0279]

RIN 1625–AA00

Safety Zone; Ohio River mile 307.8–308.8 Huntington, WV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Ohio River from mile 307.8 to mile 308.8, Huntington, WV. This temporary safety zone is necessary to protect persons and property from potential damage and safety hazards during a fireworks display on or over the navigable waterway. During the period of enforcement, entry into this safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Ohio Valley or other designated representative.

DATES: This rule is effective from 9:30 to 11:00 p.m. on July 1, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0279 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Third Class Robert Miller; telephone (304) 733–0198, email *STL-PF-MSUHUNTINGTON-MEC@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency finds good cause that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because firework displays on or over the navigable waterway pose safety concerns for waterway users. On March 7, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, "Sector Ohio Valley Annual and Recurring Safety Zones Update" (81 FR 11706). In the NPRM, the Coast Guard proposed to amend and update its list of recurring safety zone regulations that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). The public comment period ended on June 6, 2016. The Coast Guard did not receive comments on the NPRM. The Coast Guard issued a final rule on June 14, 2016, finalizing the events proposed in the NPRM, and the rule became effective on June 14, 2016 (see 81 FR 38595).

Before the comment period closed, the Coast Guard received new information regarding the Kindred Communications/Dawg Dazzle event, listed in Table 1 of 33 CFR 165.801, Line 56. For 2016, the event sponsor requested that the event be held on July 1 instead of the July 4, which was the date proposed in the NPRM. Due to the date of the event, it is impracticable to publish an NPRM for this date change because we must establish this safety zone by July 1, 2016. If the event sponsor decides to continue to hold the event annually on July 1, the Coast Guard will publish an NPRM in the **Federal Register** to permanently change the event date.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making the rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of the rule is contrary to the public interest as it would delay the effectiveness of the temporary safety zone needed to respond to potential related safety hazards until after the planned fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP has determined that potential hazards associated with fireworks displays taking place on or over this section of navigable waterway will be a safety concern for anyone within the area designated as the safety zone. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 9:30 until 11:00 p.m. on July 1, 2016 for all waters of the Ohio River from mile 307.8 to mile 308.8, for the Dawg Dazzle Fireworks Display in Huntington, WV. This safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and

Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This temporary final rule establishes a safety zone that will be enforced for a limited time period. During the enforcement period, vessels are prohibited from entering into or remaining within the safety zone unless specifically authorized by the COTP or a designated representative. Based on the location, limited safety zone size, and short duration of the enforcement period, this rule does not pose a significant regulatory impact. Additionally, notice of the safety zone or any changes in the planned schedule will be made via Broadcast Notices to Mariners and Local Notices to Mariners. Deviation from this rule may be requested from the COTP or a designated representative and will be considered on a case-by-case basis.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that the actions are one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than two hours that will limit access to a specific area on the Ohio River. This safety zone is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0279 to read as follows:

§ 165.T08–0279 Safety Zone; Ohio River, Mile 307.8 to Mile 308.8, Huntington, WV.

(a) *Location.* The following area is a safety zone: All waters of the Ohio River from mile 307.8 to mile 308.8.

(b) *Enforcement period.* This safety zone will be enforced from 9:30 p.m. until 11:00 p.m. on July 1, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley (COTP) or designated personnel. Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

(2) Persons and vessels permitted to deviate from this safety zone regulation and enter the restricted area must transit at the slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate of the enforcement period for each safety zone as well as any changes in the planned and published dates and times of enforcement.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15570 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0608]

RIN 1625–AA11

Regulated Navigation Area; Fourth of July, Biscayne Bay, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily establishing a regulated navigation area on Biscayne Bay in Miami, Florida for the Fourth of July, 2016. This regulation is necessary to protect the public during upcoming Fourth of July events, a period during which a significant concentration of persons and vessels historically operate on the waters of Biscayne Bay. To ensure the public's safety, all vessels within the regulated navigation area are required to transit the regulated navigation area at no more than 15 knots; are subject to control by the Coast Guard officers and petty officers; and are required to follow the instructions of all law enforcement vessels in the area.

DATES: This rule is effective on July 4th, 2016, from 7 p.m. until 11:59 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0608 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Benjamin Colbert, Sector Miami Waterways Management Branch, U.S. Coast Guard; telephone 305–535–4317, email *Benjamin.R.Colbert@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

Recreational boating traffic on the waters of Biscayne Bay increases significantly during Fourth of July activities. In recent years, recreational vessel speed, especially in crossing navigational channels, contributed to incidents that resulted in severe injury and death. This regulation seeks to increase public safety on the waters of Biscayne Bay during the 4th of July by requiring vessels to travel at a maximum speed of 15 knots. It also subjects recreational vessels to the control by Coast Guard officers and petty officers as well as local law enforcement authorities.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publication of an NPRM would be impracticable. During meetings with local law enforcement, only weeks prior to the holiday, it was decided that a regulated navigation area be implemented for the holiday. Local law enforcement expressed opinion that previous implementation of this rule resulted a substantially safer waterway. This late decision makes proposing the rule for comment impracticable.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register** for the reasons discussed above.

III. Legal Authority and Need for Rule

The legal basis for this proposed rule is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1. The District Seven Commander has determined that potential hazards associated with Fourth of July events pose a safety concern for anyone on the waters of Biscayne Bay. The purpose of this rule is to ensure safety of vessels and the navigable waters in Biscayne Bay before, during, and after the July 4th events.

IV. Discussion of Comments, Changes, and the Rule

This rule establishes a regulated navigational area from 7 p.m. to 11:59 on July 4th, 2016. This regulated navigation area will encompass certain waters of the Biscayne Bay between Julia Tuttle Causeway Bridge and Cutler Bay, Florida. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after Fourth of July events.

All vessels within the proposed regulated navigation area are: (1) Required to transit the regulated navigation area at no more than 15 knots; (2) subject to control by Coast Guard officers and petty officers; and (3) required to follow the instructions of all law enforcement vessels in the area.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Although the regulated navigational area covers most of Biscayne Bay, it is only enforced for five hours on a holiday evening. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to enter the regulated navigational area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 0 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated navigation area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T07–0608 to read as follows:

§ 165.T07–0608 Regulated Navigation Area; Fourth of July, Biscayne Bay, Miami, FL.

(a) *Regulated area.* The regulated navigation area encompasses all waters of Biscayne Bay between Tuttle Causeway Bridge and Black Point contained within an imaginary line connecting the following points: Beginning at Point 1 in position 25°48′38″ N, 80°10′40″ W; thence east to Point 2 in position 25°48′38″ N, 80°10′30″ W; thence southwest to Point 3 in position 25°46′41″ N, 80°10′54″ W; thence southeast to Point 4 in position 25°46′17″ N, 80°10′43″ W; thence southwest to Point 5 in position 25°45′05″ N, 80°10′50″ W; thence southeast to Point 6 in position 25°44′47″ N, 80°10′44″ W; thence southeast to Point 7 in position 25°43′29″ N, 80°09′37″ W; thence southwest to Point 8 in position 25°42′39″ N, 80°10′35″ W; thence southwest to Point 9 in position 25°31′11″ N, 80°13′06″ W; thence northwest to Point 10 in position 25°31′31″ N, 80°17′48″ W; thence northeast to Point 11 in position 25°43′25″ N, 80°13′17″ W; thence northeast to Point 12 in position 25°43′59″ N, 80°12′04″ W; thence northeast to Point 13 in position 25°44′46″ N, 80°11′23″ W; thence northeast to Point 14 in position 25°46′10″ N, 80°10′59″ W; thence northwest to Point 15 in position 25°46′20″ N, 80°11′04″ W; thence northeast to Point 16 in position 25°46′44″ N, 80°10′59″ W; thence northwest to Point 17 in position 25°47′15″ N, 80°11′06″ W; thence northeast to Point 18 in position 25°47′24″ N, 80°11′00″ W; thence north to Point 19 in position 25°47′36″ N, 80°11′00″ W; thence back to origin. All coordinates are North American Datum 1983.

(b) *Definition.* The term "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) *Regulations.* All vessels within the regulated area are required to transit at no more than 15 knots; are subject to control by the Coast Guard officers and petty officers; and must follow the instructions of designated representatives.

(d) *Enforcement period.* This section will be in enforced with actual notice from 7 p.m. to 11:59 on July 4, 2016.

Dated: June 24, 2016.

A.J. Gould,

Captain, U.S. Coast Guard, Acting Commander, Seventh Coast Guard District.

[FR Doc. 2016–15508 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0616]

RIN 1625–AA00

Safety Zone; Ohio River Mile 317–318, Ashland, KY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Ohio River from mile 317 to mile 318, Ashland, KY. This temporary safety zone is necessary to protect persons and property from potential damage and safety hazards during a fireworks display on or over a navigable waterway. During the period of enforcement entry into this safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Ohio Valley or a designated representative.

DATES: This rule is effective from 9:35 to 10:45 p.m. on July 2, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0616 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Third Class Robert Miller; telephone (304) 733–0198, email *STL-PF-MSUHUNTINGTON-MEC@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency finds good cause that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because fireworks displays on or over the navigable waterway poses safety concerns for waterway users. On March 7, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, "Sector Ohio Valley Annual and Recurring Safety Zones Update" (81 FR 11706). In the NPRM, the Coast Guard proposed to amend and update its list of recurring safety zone regulations that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). The public comment period ended on June 6, 2016. The Coast Guard did not receive comments on the NPRM. The Coast Guard issued a final rule on June 14, 2016, finalizing the events proposed in the NPRM, and the rule became effective on June 14, 2016 (see 81 FR 38595).

Before the comment period closed, the Coast Guard received new information regarding the Party in the Park event, listed in Table 1, Line 13 of 33 CFR 165.801. For 2016, the event sponsor requested that the event be held on July 2 instead of July 4, which was the date proposed in the NPRM. Due to the date of the event, it is impracticable to publish an NPRM for this date change because we must establish this safety zone by July 2, 2016. If the event sponsor decides to continue to hold the event annually on July 2, the Coast Guard will publish an NPRM in the **Federal Register** to permanently change the event date.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making the rule effective less than 30 days after publication in the **Federal Register.** Delaying the effective date of the rule is contrary to the public interest as it would delay the effectiveness of the temporary safety zone needed to respond to potential related safety hazards until after the planned fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP has determined that potential hazards associated with fireworks displays taking place on or over this section of navigable waterway will be a safety concern for anyone within the area designated as the safety zone. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 9:35 until 10:45 p.m. on July 2, 2016 for all waters of the Ohio River from mile 317 to mile 318, for the Party in the Park Fireworks Display in Ashland, KY. This safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This temporary final rule establishes a safety zone that will be enforced for a limited time period. During the enforcement period, vessels are prohibited from entering into or remaining within the safety zone unless specifically authorized by the COTP or a designated representative. Based on the location, limited safety zone size, and short duration of the enforcement period, this rule does not pose a significant regulatory impact. Additionally, notice of the safety zone or any changes in the planned schedule will be made via Broadcast Notices to Mariners and Local Notices to Mariners. Deviation from this rule may be requested from the COTP or a designated representative and will be considered on a case-by-case basis.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that the actions are one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than two hours that will limit access to a specific area on the Ohio River. This safety zone is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0616 to read as follows:

§ 165.T08–0616 Safety Zone; Ohio River, Mile 317 to Mile 318, Ashland, KY.

(a) *Location.* The following area is a safety zone: All waters of the Ohio River from mile 317 to mile 318.

(b) *Enforcement period.* This safety zone will be enforced from 9:35 until 10:45 p.m. on July 2, 2016. Actual notice will be used for enforcement purposes.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley (COTP) or designated personnel. Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

(2) Persons and vessels permitted to deviate from this safety zone regulation and enter the restricted area must transit at the slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate of the enforcement period for each safety zone as well as any changes in the planned and published dates and times of enforcement.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15572 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0502]

RIN 1625–AA00

Safety Zone; Ohio River Mile 607.5 to 608.6, Indiana

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Ohio River from mile 607.5 to mile 608.6. This temporary safety zone is necessary to protect persons and property from potential damage and safety hazards during a fireworks display on or over the navigable waterway. During the period of enforcement, entry into this safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Ohio Valley or a designated representative.

DATES: This rule is effective from 10:30 p.m. until 11:00 p.m. on July 3, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0502 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer James Robinson, Sector Ohio Valley, U.S. Coast Guard; telephone (502) 779–5347, email *James.C.Robinson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency finds good cause that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because fireworks displays on or over the navigable waterway poses safety concerns for waterway users. On March 7, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, "Sector Ohio Valley Annual and Recurring Safety Zones Update" (81 FR 11706). In the NPRM, the Coast Guard proposed to amend and update its list of recurring safety zone regulations that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). The public comment period ended on June 6, 2016. The Coast Guard did not receive comments on the NPRM. The Coast Guard issued a final rule on June 14, 2016, finalizing the events proposed in the NPRM, and the rule became effective on June 14, 2016 (see 81 FR 38595).

Before the comment period closed, the Coast Guard received new information regarding the Riverfront Independence Festival Fireworks Display, listed in Table 1 of 33 CFR 165.801, Line 21. For 2016, the event sponsor requested that the event be held at Ohio River mile 607.5 to mile 608.6 instead of Ohio River, mile 602.0 to mile 603.5, which is the location listed in the NPRM and current CFR. It is impracticable to publish a NPRM for this location change because we must establish this safety zone by July 3, 2016. If the event sponsor decides to continue to hold the event annually at Ohio River mile 607.5 to mile 608.6, the Coast Guard will publish an NPRM in the **Federal Register** to permanently change the event location.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making the rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of the rule is contrary to the public interest as it would delay the effectiveness of the temporary safety zone needed to respond to potential related safety hazards until after the planned fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP has determined that potential hazards associated with fireworks displays taking place on or over this section of navigable waterway will be a safety concern for anyone within the area designated as the safety zone. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 10:30 p.m. until 11:00 p.m. on July 03, 2016 for all waters of the Ohio River from mile 607.5 to mile 608.6, for the Riverfront Independence Festival Fireworks Display. This safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This temporary final rule establishes a safety zone that will be enforced for a limited time period. During the enforcement period, vessels are prohibited from entering into or remaining within the safety zone unless specifically authorized by the COTP or other designated representative. Based on the location, limited safety zone size, and short duration of the enforcement period, this rule does not pose a significant regulatory impact. Additionally, notice of the safety zone or any changes in the planned schedule will be made via Broadcast Notices to Mariners and Local Notices to Mariners. Deviation from this rule may be requested from the COTP or other designated representative and will be considered on a case-by-case basis.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that the actions are one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than two hours that will limit access to a specific area on the Ohio River. This safety zone is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0502 to read as follows:

§ 165.T08–0502 Safety Zone; Ohio River, Mile 607.5 to Mile 608.6.

(a) *Location.* The following area is a safety zone: All waters of the Ohio River from mile 607.5 to mile 608.6.

(b) *Enforcement period.* This safety zone will be enforced from 10:30 p.m. until 11:00 p.m. on July 3, 2016.

(c) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Ohio Valley in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or designated representative via VHF–FM radio channel 16 or phone at 1–800–253–7465.

(3) All persons and vessels shall comply with the instruction of the COTP and designated on-scene personnel.

(e) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate of the enforcement period for each safety zone as well as any changes in the planned and published dates and times of enforcement.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15571 Filed 6–29–16; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 233

Inspection Service Authority; Civil Monetary Penalty Inflation Adjustment

AGENCY: Postal Service.

ACTION: Interim final rule.

SUMMARY: This rule updates postal regulations to implement inflation adjustments to civil monetary penalties that may be imposed under consumer protection and mailability provisions enforced by the Postal Service pursuant to the Deceptive Mail Prevention and Enforcement Act and the Postal Accountability and Enhancement Act. These adjustments are required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. This notice also includes the statutory civil monetary penalties subject to the 2015 Act.

DATES: *Effective date:* August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Steven Sultan, (202) 268–7385.

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), Public Law 114–74, 129 Stat. 584, amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (1990 Act), Public Law 101–410, 104 Stat. 890 (28 U.S.C. 2461 note), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Section 3 of the 1990 Act specifically includes the Postal Service in the definition of "agency" subject to its provisions.

The 2015 Act requires the Postal Service to make two types of adjustments to civil penalties that meet the definition of "civil monetary penalty" under the 1990 Act. The Office of Management and Budget has furnished detailed instructions regarding these adjustments in memorandum M–16–06, *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2016* (February 24, 2016), *www.whitehouse.gov/omb/memoranda/2016/m-16-06.*

First, the Postal Service must make an initial "catch-up" adjustment to each of its qualifying civil monetary penalties through an interim final rule by July 1, 2016. The catch-up adjustment is based on the Consumer Price Index (CPI–U) and is calculated for each penalty. The amount of the adjustment is calculated by multiplying the current published penalty amount by an adjustment factor provided by the Office of Management and Budget (OMB). The adjustment factor varies depending on the year a penalty was last adjusted. The new penalty amount must be rounded to the nearest dollar.

Second, the Postal Service must make an annual adjustment for inflation and publish the adjustment in the **Federal Register** by January 15 of each year, beginning in 2017. Each penalty will be adjusted as instructed by OMB based on CPI–U from the most recent October.

The 2015 Act allows the interim final rule and annual inflation adjustments to be published without prior public notice or opportunity for public comment.

Adjustments to Postal Service Civil Monetary Penalties

Civil monetary penalties may be assessed for postal offenses under sections 106 and 108 of the Deceptive Mail Prevention and Enforcement Act, Public Law 106–168, 113 Stat. 1811, 1814 (*see,* 39 U.S.C. 3012(a), (c)(1), (d), and 3017(g)(2), (h)(1)(A)); and section 1008 of the Postal Accountability and Enhancement Act, Public Law 109–435, 120 Stat. 3259–3261 (*see,* 39 U.S.C. 3018 (c)(1)(A)). The statutory civil monetary penalties subject to the 2015 Act and the amount of each penalty after the "catch-up" adjustment are as follows:

39 U.S.C. 3012(a)—False representations and lottery orders.

Under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may issue administrative orders prohibiting persons from using the mail to obtain money through false representations or lotteries. Persons who evade, attempt to evade, or fail to comply with an order to stop such prohibited practices may be liable to the United States for a civil penalty under 39 U.S.C. 3012(a). This section currently imposes a $50,000 penalty for each mailing less than 50,000 pieces, $100,000 for each mailing 50,000 to 100,000 pieces, and $10,000 for each piece above 100,000 up to a penalty of $2,000,000. These penalties were last adjusted in 2000. Based on the guidance in OMB memorandum M–16–06, an adjustment multiplier of 1.36689 will be used. The new penalties will be as follows: $68,345 for each mailing less than 50,000 pieces, $136,689 for each mailing of 50,000 to 100,000 pieces, and $13,669 for each piece above 100,000 not to exceed $2,733,780.

39 U.S.C. 3012(c)(1)—False representation and lottery penalties in lieu of or as part of an order.

In lieu of or as part of an order issued under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may assess a civil penalty. Currently, the amount of this penalty, set in 39 U.S.C. 3012(c)(1), is $25,000 for each mailing that is less than 50,000 pieces, $50,000 for each mailing of 50,000 to 100,000 pieces, and an additional $5,000 for every additional 10,000 pieces above 100,000 not to exceed $1,000,000. These penalties were last adjusted in 2000. Based on OMB guidance, an adjustment multiplier of 1.36689 will be used. The new penalties will be $34,172 for each mailing that is less than 50,000 pieces, $68,345 for each mailing of 50,000 to 100,000 pieces, and an additional $6,834 for every additional 10,000 pieces above 100,000 not to exceed $1,366,890.

39 U.S.C. 3012(d)—Misleading references to the United States Government; Sweepstakes and deceptive mailings.

Persons sending certain deceptive mail matter described in 39 U.S.C. 3001((h)–(k), including:

- Solicitations making false claims of Federal Government connection or approval;
- Certain solicitations for the purchase of a product or service that may be obtained without cost from the Federal Government;
- Solicitations containing improperly prepared "facsimile checks"; and
- Certain solicitations for "skill contests" and "sweepstakes" sent to individuals who, in accordance with 39 U.S.C. 3017(d), have requested that such materials not be mailed to them);

may be liable to the United States for a civil penalty under 39 U.S.C. 3012(d). Currently, this penalty is not to exceed $10,000 for each mailing. The penalty was last adjusted in 2000. Based on OMB guidance, an adjustment multiplier of 1.36689 will be used. The new penalty will be $13,669.

39 U.S.C. 3017(g)(2)—Commercial use of lists of persons electing not to receive skill contest or sweepstakes mailings.

Under 39 U.S.C. 3017(g)(2), the Postal Service may impose a civil penalty against a person who provides information for commercial use about individuals who, in accordance with 39 U.S.C. 3017(d), have elected not to receive certain sweepstakes and contest information. Currently, this civil penalty may not exceed $2,000,000 per violation. The penalty was last adjusted in 2000. Based on OMB guidance, an adjustment multiplier of 1.36689 will be used. The new penalty may not exceed $2,733,780 per violation.

39 U.S.C. 3017(h)(1)(A)—Reckless mailing of skill contest or sweepstakes matter.

Currently, under 39 U.S.C. 3017(h)(1)(A), any promoter who recklessly mails nonmailable skill contest or sweepstakes matter may be liable to the United States in the amount of $10,000 per violation for each mailing to an individual. The penalty was last adjusted in 2000. Based on OMB guidance, an adjustment multiplier of 1.36689 will be used. The new penalty is $13,669 per violation.

39 U.S.C. 3018(c)(1)(A)—Hazardous material.

Under 39 U.S.C. 3018(c)(1)(A), the Postal Service may impose a civil penalty payable into the Treasury of the United States on a person who knowingly mails nonmailable hazardous materials or fails to follow postal laws on mailing hazardous materials. Currently, this civil penalty is at least $250, but not more than $100,000 for each violation. The penalty amounts were last adjusted in 2006. Based on OMB guidance, an adjustment multiplier of 1.17858 will be used. The new penalty is at least $295, but not more than $117,858 for each violation.

List of Subjects in 39 CFR Part 233

Administrative practice and procedure, Banks, Banking, Credit, Crime, Infants and children, Law enforcement, Penalties, Privacy, Seizures and forfeitures.

For the reasons set out in this document, the Postal Service amends 39 CFR part 233 as follows:

PART 233—INSPECTION SERVICE AUTHORITY

■ 1. The authority citation for 39 CFR part 233 is revised to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005, 3012, 3017, 3018; 12 U.S.C. 3401–3422; 18 U.S.C. 981, 983, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Pub. L. 101–410, 104 Stat. 890; Pub. L. 104–208, 110 Stat. 3009–378; Pub. L. 106–168, 113 Stat. 1806; Pub. L. 114–74, 129 Stat. 584.

■ 2. Revise § 233.12 to read as follows:

§ 233.12 Civil penalties.

(a) *False representations and lottery orders.* Under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may issue administrative orders prohibiting persons from using the mail to obtain money through false representations or lotteries. Persons who evade, attempt to evade, or fail to comply with an order to stop such prohibited practices may be liable to the United States for a civil penalty under 39 U.S.C. 3012(a). As adjusted under Public Law 114–74, the penalties are as follows: $68,345 for each mailing less than 50,000 pieces, $136,689 for each mailing of 50,000 to $100,000 pieces, and $13,669 for each piece above 100,000 not to exceed $2,733,780.

(b) *False representation and lottery penalties in lieu of or as part of an order.* In lieu of or as part of an order issued under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may assess a civil penalty payable under 39 U.S.C. 3012(c)(1). As adjusted under Public Law 114–74, the penalties are as follows: $34,172 for each mailing that is less than 50,000 pieces, $68,345 for each mailing of 50,000 to 100,000 pieces, and an additional $6,834 for every additional 10,000 pieces above 100,000 not to exceed $1,366,890.

(c) *Misleading references to the United States Government; Sweepstakes and deceptive mailings.* Persons sending certain deceptive mail matter described in 39 U.S.C. 3001(h)–(k), including:

(1) Solicitations making false claims of Federal Government connection or approval;

(2) Certain solicitations for the purchase of a product or service that may be obtained without cost from the Federal Government;

(3) Solicitations containing improperly prepared "facsimile checks"; and

(4) Solicitations for "skill contests" and "sweepstakes" sent to individuals who, in accordance with 39 U.S.C. 3017(d), have requested that such materials not be mailed to them; may be liable to the United States for a civil penalty under 39 U.S.C. 3012(d). As adjusted under Public Law 114–74, this penalty is not to exceed $13,669 for each mailing.

(d) *Commercial use of lists of persons electing not to receive skill contest or sweepstakes mailings.* Under 39 U.S.C. 3017(g)(2), the Postal Service may impose a civil penalty against a person who provides information for commercial use about individuals who, in accordance with 39 U.S.C. 3017(d), have elected not to receive certain sweepstakes and contest information. As adjusted under Public Law 114–74, the penalty may not exceed $2,733,780 per violation.

(e) *Reckless mailing of skill contest or sweepstakes matter.* Under 39 U.S.C. 3017(h)(1)(A), any promoter who recklessly mails nonmailable skill contest or sweepstakes matter may be liable to the United States for a civil penalty for each mailing to an individual. As adjusted under Public Law 114–74, the penalty is $13,669 per violation.

(f) *Hazardous material.* Under 39 U.S.C. 3018(c)(1)(A), the Postal Service may impose a civil penalty payable into the Treasury of the United States on a person who knowingly mails nonmailable hazardous materials or fails to follow postal laws on mailing hazardous materials. As adjusted under Public Law 114–74, the penalty is at least $295, but not more than $117,858 for each violation.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15464 Filed 6–29–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL REGULATORY COMMISSION

39 CFR Parts 3000, 3001, and 3008

[Docket No. RM2016–4; Order No. 3379]

Ex Parte Communications

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a set of final rules amending existing Commission rules related to ex parte communications. The final rules are consistent with the recommended approach to agency treatment of ex parte communications. Relative to the proposed rules, some rules were restructured based on comments received, others were modified to alleviate confusion.

DATES: *Effective* August 1, 2016.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Regulatory History

81 FR 1931, January 14, 2016.

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I. Introduction

In this Order, the Commission adopts final rules concerning ex parte communications. The final rules adopted by this Order amend existing Commission rules and remove obsolete rules no longer applicable under the Postal Accountability and Enhancement Act (PAEA), Public Law 109–435, 120 Stat. 3218 (2006). The final rules are located at 39 CFR part 3008. Existing rules located at §§ 3000.735–501, 502, 3001.5(o), and 3001.7 are amended to reflect the revised location of the ex parte communications rules. Existing rules located at 39 CFR part 3000 are renumbered for consistency with **Federal Register** guidance.

The rules as adopted incorporate suggestions offered by commenters that restructure some rules as proposed, but do not materially affect their substance. The initial approach taken by the Commission was to codify only what were considered mandatory ex parte communications requirements in the Code of Federal Regulations (CFR) applicable to a limited set of Commission docket types. The Commission also proposed to issue a more comprehensive policy document to include ex parte communications requirements for other possible docket types.[1] The Commission understands comments suggesting the proposed approach would cause confusion concerning when the mandatory rules apply versus when the policy applies. The Commission has adopted modified rules to alleviate this confusion by making the rules inclusive of all proceeding types before the Commission with specific exceptions. This is a change in form, but not substance.[2]

The change in structure also is intended to clarify that the Commission in most instances will effectively take a permit-but-disclose approach to ex parte communications, which was suggested by many of the commenters. However, given the opportunities the Commission provides to participants to avoid ex parte communications issues altogether, the rules do not encourage ex parte communications as the norm.[3] The proposed changes in structure also are intended to clarify that penalties for violating ex parte communication rules only apply to very limited proceeding types.

II. Background

On January 8, 2016, the Commission issued Order No. 3005, introducing a proposed revision and reorganization of its rules concerning ex parte communications. *See* Order No. 3005. Order No. 3005 explained that the current rules concerning ex parte communications are located at §§ 3000.735–501, 502, and 3001.7. *See id.* The Commission identified a need to revise the existing rules for several reasons. The existing rules contained significant redundancy between the requirements of § 3000.735–501 and the requirements of § 3001.7. Furthermore, the existing rules made it difficult to identify who qualified as Commission "decision-making personnel" without referring to unrelated sections of the CFR.

The existing rules also referred to rate and classification cases under 39 U.S.C. 3624, which were eliminated under the PAEA. Finally, the existing rules lacked guidance for Commission personnel on how to treat ex parte communications falling outside the scope of the specific docket types mentioned.

The operative statute requires the Commission to restrict ex parte communications only in matters where the Commission must provide an opportunity for a hearing on the record pursuant to 5 U.S.C. 556 through 557. Under the PAEA, the Commission is only required to provide an opportunity for a hearing in matters regarding a change in the nature of postal services pursuant to 39 U.S.C. 3633. In addition to nature of service matters, Commission regulations historically have extended restrictions on ex parte communications to post office appeal cases pursuant to 39 U.S.C. 404(d)(5) and (6) and complaint cases pursuant to 39 U.S.C. 3662. The Commission considers the restriction appropriate because of the potential impact ex parte communications might have on participants and their associated rights in those types of proceedings. *See* Order No. 3005 at 2–3.

In addition to the above three types of proceedings—nature of service, post office closings, and complaints—many other types of proceedings come before the Commission. Accordingly, the Commission attached as a library reference to Order No. 3005 a new proposed internal policy on the treatment of ex parte communications applicable to all cases. For consistency with prevailing principles regarding agency treatment of ex parte communications,[4] and for simplicity and efficiency of administration, the Commission policy requires Commission personnel to treat ex parte communications similarly in all proceeding types. In Order No. 3005, the Commission sought public comment on the proposed rules and the attached internal policy.[5]

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[1] The opportunity to comment on both the rules and the policy were provided in Order No. 3005. Notice of Proposed Rulemaking Regarding Ex Parte Communications, January 8, 2016 (Order No. 3005).

[2] The Commission's internal policy is revised to reflect the changes in the final rules and will be made available on the Commission's Web site.

[3] For example, participants generally have sufficient opportunities to make their views known by filing documents on the Commission's Web site during the course of a proceeding.

The commenters provide instructive perspectives on the Commission's proposed rules. Notably, the commenters alert the Commission to the confusion caused by proposing both an internal policy applicable to all cases and enforceable only on Commission personnel, and regulations applicable only to specific types of cases and applicable to all persons. This final Order is intended to remedy the confusion surrounding when ex parte restrictions apply, and when and what penalties may be imposed. The changes to the proposed rules reflect the input of the commenters but do not materially change the operation of the proposed rules. The final rules formalize, but do not materially change, the Commission's current practice for handling ex parte communications.

III. Comments

On February 29, 2016, the Commission received comments from the Postal Service,[6] the Public Representative,[7] MPA—the Association of Magazine Media (MPA),[8] and a group of interested mailer organizations (Joint Commenters).[9] On March 15, 2016, the Commission received reply comments from the Postal Service[10] and the Public Representative.[11]

While the commenters either support the Commission's effort or find it reasonable for the Commission to ensure that its rules concerning ex parte communications promote transparency and fairness,[12] several commenters have concerns regarding the scope of the restrictions of the proposed rules and internal policy. *See* Postal Service Comments at 2, 3–7; Joint Comments at 5–7.

A. Types of Proceedings to Which the Prohibition Against Ex Parte Communications Applies

The Postal Service, MPA, and the Joint Commenters each express concern that the Commission policy treating all case types similarly is more restrictive than is necessary. *See* Postal Service Comments at 3–7; MPA Comments at 2–5; Joint Comments at 4–5. They note that the Administrative Procedure Act (APA) expressly prohibits ex parte communications in formal rulemakings only. Postal Service Comments at 3; MPA Comments at 3; Joint Comments at 4. The Postal Service, MPA, and the Joint Commenters appear to agree that the proposed rules unnecessarily restrict desirable communications in informal proceedings. *See* Postal Service Comments at 3; MPA Comments at 3; Joint Comments at 3. Each discuss *Sierra Club* v. *Costle,* 657 F.2d 298 (D.C. Cir. 1981), to emphasize the value of informal agency contacts with public stakeholders in regulated industry communities. *See* Postal Service Comments at 7; MPA Comments at 3; Joint Comments at 3. The Postal Service, MPA, and the Joint Commenters express concern that the Commission's policy is not in accord with Recommendation 2014–4. Postal Service Comments at 5–7; MPA Comments at 4–5; Joint Comments at 6. The Joint Commenters state that "[t]he proposed prohibition on *ex parte* communications in informal rulemakings is inconsistent with the long-standing recommendation of the Administrative Conference and the prevailing practice among other federal agencies." Joint Comments at 7. The Public Representative suggests that enforceability of the internal policy as it affects nonemployees is a potential issue. PR Comments at 5.

The Postal Service proposes several modifications to the proposed rules. The Postal Service recommends that ex parte communications be prohibited only "in 'contested proceedings' where there are material issues in dispute." Postal Service Comments at 10. It also proposes that the Commission's decision to apply the restrictions to a particular proceeding should be based upon specific criteria and that the Commission should give notice when the rules will apply. *Id.* The Postal Service proposes that the definition of an ex parte communication be limited to those "regarding the merits" of a matter before the Commission. *Id.* at 14. Another Postal Service proposal suggests exempting communications regarding general issues of domestic or international postal policy, postal operations, or other statutory responsibilities not associated with the merits of a contested proceeding. *Id.* at 15.

In her reply comments, the Public Representative raises concerns about the applicability of the rationale discussed in *Sierra Club.* PR Reply Comments at 2. Though the D.C. Circuit noted several benefits in allowing or encouraging informal communications with regulatory agencies, the Public Representative notes that the Commission has a "relatively unique mission" and generally does not conduct the type of large-scale programs to which the Court may have been referring. *Id.* The Public Representative also states that the Commission's authority typically does not include exercising the same type of industry enforcement action, such as imposing fines or other penalties for failing to meet federal standards. *Id.* The Public Representative notes that one of the Court's stated benefits to allowing ex parte communication was "[s]purring the provision of information which the agency may need." *Id.* (quoting *Sierra Club,* 657 F.2d 298 at 401). The Public Representative lists current Commission practices highlighting the Commission's commitment to seeking information from outside sources, including providing an opportunity for reply comments in almost all dockets, "extremely generous policy" of granting extensions of time to file comments, acceptance of late-filed comments, and reconsideration of stated opinions. PR Reply Comments at 2. The Public Representative characterizes the Commission as going to "considerable effort to accommodate on-the-record input from those who wish to weigh in on a matter within the Commission's jurisdiction." *Id.* at 3.

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[4] Library Reference PRC–LR–RM2016–4/1, January 8, 2016. *See* Esa L. Sferra-Bonistalli, *Ex Parte Communications in Informal Rulemaking,* May 1, 2014 (prepared for consideration of the Administrative Conference of the United States); Administrative Conference of the United States, Administrative Conference Recommendation 2014–4, June 6, 2014 (Recommendation 2014–4).

[5] Order No. 3005 at 8. The Commission granted the Postal Service's request for an extension of time to file comments through February 29, 2016, and to file reply comments through March 15, 2016. Order No. 3076, Order Granting Extension of Time to File Comments, February 12, 2016. *See* Motion for Extension of Time to Submit Comments on Proposed Ex Parte Communications Rulemaking, February 11, 2016.

[6] United States Postal Service Comments on Proposed Ex Parte Communications Rules, February 29, 2016 (Postal Service Comments).

[7] Public Representative's Comments, February 29, 2016 (PR Comments).

[8] Comments of MPA—The Association of Magazine Media, February 29, 2016 (MPA Comments).

[9] Joint Comments of the Association of Mail Electronic Enhancement, the American Catalog Mailers Association, Inc., the Association of Postal Commerce, the Direct Marketing Association, Envelope Manufacturers Association, Epicomm, IDEAlliance, the Major Mailers Association, National Postal Policy Council, News Paper Association of America, Parcel Shippers Association, Saturation Mailers Coalition, the American Forest & Paper Association, and the National Association of Presort Mailers, February 29, 2016 (Joint Comments).

[10] Reply Comments of the United States Postal Service, March 15, 2016 (Postal Service Reply Comments).

[11] Public Representative's Reply Comments, March 15, 2016 (PR Reply Comments).

[12] *See* Postal Service Comments at 2 ("The Postal Service strongly supports the principles of transparency and fairness the proposed rules and policy are intended to promote. . . ."); PR Comments at 4 ("The Public Representative supports the Commission's interest in taking a fresh look at . . . ex parte communications in light of the enactment of the PAEA in 2006. . . ."); MPA Comments at 1 ("The Commission's decision to review and revise its current ex parte rules is reasonable."); Joint Comments at 3 ("The Joint Commenters support the goal of promoting the transparency and integrity of proceedings before the Commission.").

B. When Matters Are Before the Commission

The commenters express concern regarding vagueness in when a matter will be considered to be "before the Commission." MPA states that most agencies do not consider a matter to be before the agency "until it has issued a formal notice of the commencement of the proceeding, an interested person has filed a complaint or formal request that the agency begin the proceeding, or a person has actual knowledge that the proceeding will be noticed." MPA Comments at 5. MPA states the proposed rules do not adequately define the terms "expected," "actively preparing," and "reasonable period of time." *Id.* at 6.

The Joint Commenters state that Recommendation 2014–4 recommends agencies not impose restrictions on ex parte communications before notice is issued. Joint Comments at 6. The Postal Service criticizes the proposed rules' definition of when a matter is before the Commission, expressing concern that certain docket types involve the filing of periodically required reports, namely the Annual Compliance Report. Postal Service Comments at 16. The Postal Service states that because the scope of the Annual Compliance Report is so broad, the proposed rules would prohibit the Postal Service from ever having an off-the-record discussion about costs, revenues, rates, or quality of service, because of the knowledge that proceeding will be before the Commission annually. *Id.* at 16–17. The Postal Service proposes an amendment to proposed § 3008.3(c)(4), adding that knowledge of the regular filing of periodic reports does not place a matter before the Commission. *Id.* at 17. Similarly, the Public Representative questions whether the predictability of certain periodic filings necessarily puts participants on notice of certain proceedings. PR Comments at 6–7.

C. Recommended Approach: Permit but Disclose

Several commenters note that the Administrative Conference of the United States considers a general prohibition on ex parte communications to be undesirable. *See, e.g.,* MPA Comments at 4; Joint Comments at 7. The Postal Service, MPA, and the Joint Commenters each suggest an approach more comparable to the approach employed by other agencies.

The Postal Service lists the approaches taken by the Department of Justice (DOJ), Federal Communications Commission (FCC), and Federal Energy Regulatory Commission (FERC). Postal Service Comments at 6–7. The Postal Service states the FERC limits ex parte restrictions to "contested on-the-record proceedings," while the FCC classifies informal rulemakings as "permit-but-disclose" proceedings, and the DOJ permits ex parte communications subject to disclosure. *Id.* at 7 (quoting 18 CFR 385.2201; 47 CFR 1.1206; and 28 CFR 50.17(b) through (c), respectively).

MPA suggests that the Commission need not go as far as the FERC, identifying a common alternative of permitting ex parte communications but requiring public disclosure of their substance. MPA Comments at 4. Similarly, the Joint Commenters state that "[t]he Commission's proposed rules should be revised, consistent with APA requirements for reasoned decision making, to allow the Commission to permit but disclose any *ex parte* communications that it relies on in the context of an informal rulemaking proceeding." Joint Comments at 8.

In its reply comments, the Postal Service suggests that Executive Order 11570, issued by President Nixon shortly after the enactment of the Postal Reorganization Act of 1970, and referenced in the Public Representative's comments, may have "envisioned the 'permit-but-disclose' approach" rather than an outright prohibition. Postal Service Reply Comments at 4.

D. Penalties

The Public Representative expresses concern about the enforceability of the internal policy on individuals outside the Commission. PR Comments at 5. Although in Order No. 3005 the Commission stated that the policy "will not be binding on persons outside of the Commission," it is evident from the comments that there is uncertainty and ambiguity regarding the applicability of certain restrictions across both the rules and internal policy. *See* Order No. 3005 at 8.

MPA, in its discussion of the ambiguity of the definition of a matter before the Commission, alludes to the "potentially draconian consequences of an adverse Commission finding." MPA Comments at 6. The Joint Commenters state that the penalties listed in proposed §§ 3008.7(a) and (b) "may be appropriate in the context of an improper *ex parte* contact in an adjudicatory proceeding, but they are excessive in the context of an informal rulemaking." Joint Comments at 8–9. The Joint Commenters fear the penalties would be "especially punitive" where the communication was made prior to notice of the informal rulemaking. *Id.* at 9.

E. Postal Service's Proposed Changes to the January 2016 Proposed Rule

The Postal Service includes its own proposed rules regarding ex parte communications. Postal Service Comments, Appendix A (Postal Service Proposed Rules). The proposed rules are a "redline" revision of the Commission's proposed rules and include line changes in particular sections.

1. Part 3000, Subpart B

Postal Service Proposed Rule 3000.735–501(a) changes the description of the Commission's internal policy to read that the policy applies only to interactions "regarding the merits of certain contested proceedings" before the Commission. Postal Service Proposed Rules 3000.735–501(b) and 3000.735–502 remain unchanged from the Commission's proposed rules.

2. Section 3008.1

The Postal Service does not propose to change the applicability provisions of proposed §§ 3008.1(a) through (d). However, Postal Service Proposed Rule 3008.1(e) narrows the scope of the Commission's proposed rule. The Postal Service's revision states that:

> [a]ny other *contested proceeding* in which the Commission, in its discretion, determines that it is appropriate to apply the rules of this section *based on considerations of fairness or for other reasons, and provides notice on the public record of the proceeding that the rules of this section will apply (and the reasons therefor). For purposes of this section, "contested proceeding" means any docketed proceeding before the Commission in which there are multiple adverse parties and/or disputed issues of fact, law or policy.*

This revision adds specific conditions for the application of ex parte restrictions, including the type and subject of a matter before the Commission.

3. Section 3008.2

The Postal Service's proposed revisions to proposed § 3008.2(a), setting forth the definition of ex parte communications, include adding the qualifier that the communication be one "regarding the merits of a matter" before the Commission. Postal Service

Proposed Rule 3008.2. The Postal Service defines a communication "regarding the merits" as "one that is intended to affect, or capable of affecting the outcome of a proceeding, or intended to influence, or capable of influencing a Commission decision on any substantive issue in the proceeding." Postal Service Proposed Rule 3008.2(a).

Postal Service Proposed Rule 3008.2(b) makes a minor revision to proposed § 3008.2(b)(3) and adds two exceptions to the definition of ex parte communications. Proposed § 3008.2 states the exception for communications made during off-the-record technical conferences where public notice of the event is provided and the event is open to all persons participating in the matter. The Postal Service's proposed change revises the exception to read that the event must be open to all persons participating in the matter before the Commission "as a party, intervenor, or Public Representative." Postal Service Proposed Rule 3008.2(b)(3).

The Postal Service removes proposed § 3008.2(b)(5), "communications not material to the matter before the Commission," and adds the following two exceptions, located at §§ 3008.2(b)(5) and (6):

> *(5) Questions or comments seeking to explain or clarify the meaning or operation of a statement, term, technical reference, or description of methodology used by the Commission or a participant in a proceeding, or to ascertain or confirm the accuracy of the Commission's (or participant's) understanding or interpretation of it; and*
>
> *(6) Communications regarding general issues of domestic or international postal policy, postal operations, or other statutory responsibilities of the Commission not associated with proceedings identified in part 3008.1 of this chapter.*

The Postal Service states the Commission's proposed § 3008.2(b)(5) is not well defined and would be unnecessary if ex parte communications were limited to those "regarding the merits." Postal Service Comments at 14. The Postal Service suggests the sixth exception to allow for general discussions about the postal industry. *Id.* at 15.

4. Section 3008.3

The Postal Service proposes that the definition of a matter before the Commission not include matters where the person "has knowledge that a request to initiate a proceeding is expected to be filed." *See id.* at 17. Postal Service Proposed Rule 3008.3 removes the Commission's proposed § 3008.3(b). The Postal Service also proposes removing the explanation that the mere potential that a request may be filed does not place a matter before the Commission, and that an affirmative action or actively preparing a request with the intent to file must exist. *Id.* at 16.

Alternatively, the Postal Service suggests amending § 3008.3(c)(4) by adding that "mere knowledge that a periodic report will be filed at regular intervals as required by statute or regulation" does not place a matter before the Commission. *Id.*

5. Section 3008.4

The Postal Service does not propose any revisions to proposed § 3008.4, defining the persons subject to the ex parte communications rules.

6. Section 3008.5

The Postal Service proposes to amend the prohibitions set forth in proposed § 3008.5. Postal Service Proposed Rule 3008.5(a) narrows the scope of prohibited communications to only those "regarding the merits of a matter before the Commission." Postal Service Proposed Rule 3008.5(a).

The Postal Service also proposes to revise proposed § 3008.5(b), regarding the Commission's reliance on information obtained through ex parte communications. Where the Commission's proposed rule prohibits reliance on information obtained through ex parte communications, the Postal Service proposes to allow reliance if certain circumstances are present, most notably the opportunity for rebuttal. Postal Service Comments at 19–20. Postal Service Proposed Rule 3008.5(b) reads as follows:

> Commission decision-making personnel *may* rely upon information obtained through ex parte communications *in determining the merits of a proceeding only where the communications are made part of the record pursuant to part 3008.6(b), where an opportunity for rebuttal has been provided pursuant to part 3008.6(d), and where reliance on the information will not cause undue delay or prejudice to any party.*

The Postal Service states that the revision allows the Commission to consider "highly relevant" statements potentially made by those unfamiliar with Commission practice. Postal Service Comments at 19. Furthermore, the Postal Service states that proposed § 3008.6(c), allowing the Commission to disregard a factual assertion or rebuttal, presupposes that the Commission may, in some circumstances, decide to consider the information. *Id.*

Proposed § 3008.5(c) is unchanged by the Postal Service's proposed revisions.

7. Section 3008.6

The Postal Service proposes extensive revisions to proposed § 3008.6. In proposed § 3008.6(a), the Postal Service proposes to change the Commission "will not" to the Commission "may not" consider an ex parte communication. Postal Service Proposed Rule 3008.6(a).

The Postal Services raises concerns about the treatment of sensitive or confidential information submitted in an ex parte communication. Postal Service Comments at 17–18. Postal Service Proposed Rule 3008.6(b) reflects this concern, as the Postal Service includes proposed guidance for the treatment of sensitive information. The Postal Service's adds, in redline, the following:

> (b) Commission decision-making personnel who receive, or who make or knowingly cause to be made, ex parte communications prohibited by this part shall *immediately notify all participants that the communications will need to be disclosed on the public record, and provide an opportunity for the participants to apply for non-public treatment of any materials or information protected from disclosure under applicable law. Any such application shall be submitted to the Commission within five business days after notification. The Commission decision-making personnel shall then* promptly place, or cause to be placed, on the public record of the proceeding:
>
> (1) All such written communications;
>
> (2) Memoranda stating the substance of all such oral communications, *including the names of all participants and the date(s) of such communications;*
>
> . . .
>
> (4) *In placing information or materials in the public record under this part, the Commission shall withhold any non-public information that a participant in the communication has demonstrated is exempt from disclosure under applicable laws, and file the non-public information under seal pursuant to the procedures identified in its rules of practice and procedure.*

The Postal Service also adds a requirement upon receipt of communications seeking to explain or clarify the meaning as set forth in Postal Service Proposed Rule 3008.2(b)(5), where the comment ultimately influences the Commission decision. Postal Service Proposed Rule 3008.6(c) reads as follows:

> *Commission decision-making personnel who receive, or who make or knowingly cause to be made, communications that are described in part 3008.2(b)(5) of this chapter shall follow the disclosure requirements set forth herein in part 3008.6(b) in the event that such communications affect the outcome of the proceeding or influence the Commission's decision on any substantive issue in the proceeding.*

The Postal Service proposes to move the Commission's proposed § 3008.6(c) regarding opportunity for rebuttal to § 3008.6(d) but does not otherwise amend the rule.

8. Section 3008.7

The Postal Service does not propose any amendments to proposed § 3008.7 regarding penalties for violations of the ex parte communication rules.

F. Additional Comments

The Public Representative points to Recommendation 2014–4, suggesting that agencies should explain whether social media communications fall within the rules' definition of ex parte communications. PR Comments at 7. The Public Representative also provides background information on the Commission's authority for its existing rules, as well as the Administrative Conference of the United States and its relevant report and recommendation. *Id.* at 8–13.

The Public Representative suggests conforming the numerical designation of the rules in 39 CFR part 3000 consistent with the **Federal Register**'s current preferences. *Id.* at 14. The Public Representative recommends replacing the hyphenated six-digit extensions with standard one-or-two-digit extensions. *Id.*

IV. Commission Analysis

A. Application of Rules Concerning Ex Parte Communications and Penalties for Violations

The changes to the proposed rules reflect the Commission's recognition of a key area of concern outlined in the submitted comments. Notably, the proposed rules left uncertainty regarding whether ex parte communications were prohibited in all cases and whether penalties were appropriate for violations in informal rulemaking proceedings.

Although the proposed rules were intended only to strictly prohibit ex parte communications in three particular types of matters (nature of service proceedings, appeals of post office closing and consolidations, and rate or service complaints), the Commission recognizes that proposed § 3008.1(e) left broad discretion to the Commission to apply the rules to any case. Such broad authority coupled with the guidance set forth in the internal policy gave the impression that the Commission could apply the ex parte prohibition and impose penalties for violations in any matter.

Such an interpretation is not the intent of this rulemaking, and therefore clarification and revision are required. The rulemaking is intended to align the Commission's rules with prevailing agency practices and clear the existing rules of redundancy and obsolete references. This rulemaking was not implemented to change, as a practical matter, the status quo for the treatment of ex parte communications. Essentially, this rulemaking was intended to codify the ex parte practices that the Commission has followed for many years.

Several commenters share concern over "draconian" penalties potentially applied in informal rulemakings. *See, e.g.,* MPA Comments at 6; Joint Comments at 6–7. The final rules address this concern. Final § 3008.1 makes clear that the ex parte restrictions will indeed apply to all cases other than the listed exceptions or cases exempted by order. However, the change to the provision for penalties specifically states that the penalties will not apply to cases other than the three specific types of proceedings listed.

In operation, the final rules create three classes of proceedings before the Commission. The first class includes nature of postal service proceedings (N cases), appeals of postal service decisions to close or consolidate post offices (A cases), and rate or service complaints (C cases). These proceedings will be subject to the ex parte rules, and any ex parte communications occurring in these proceedings will be subject to the penalties set forth in §§ 3008.7(b) and (c).

The second class of proceeding includes public inquiry proceedings (PI cases) and international mail proceedings (IM cases) undertaken pursuant to 39 CFR part 3017. Due to the highly collaborative nature of these proceedings and practical limitations on the ability to disclose each and every communication in these proceedings,[13] the ex parte rules do not apply. Off-the-record communications in these proceedings are expected and permitted. The Commission may also, when circumstances warrant, suspend the application of the ex parte rules in other particular cases.

The third class of proceeding includes all other case types before the Commission (Annual Compliance Review (ACR), Competitive Products (CP), Mail Classification (MC), Market Test (MT), Rate (R), Rulemaking (RM), and Tax Computation (T)). The ex parte rules will apply to these proceedings, but ex parte communications received by the Commission will not be subject to the penalties set forth in § 3008.7. Instead, the communication will be disclosed pursuant to § 3008.6(b). In this way, the rules will operate similarly to the "permit-but-disclose" approach suggested by the Postal Service, MPA, and the Joint Commenters.[14]

While the Commission understands and appreciates the benefits of sharing information and promoting a candid dialogue on key issues,[15] the Commission, as a matter of policy, prefers that those benefits be achieved through on-the-record communications. Indeed, as the Public Representative notes, the Commission has demonstrated a commitment to providing opportunities for all interested parties to participate in informal rulemakings. *See* PR Comments at 2–3. The preference for on-the-record discourse is consistent with, and supportive of, the Commission's mission to "[e]nsure transparency and accountability of the United States Postal Service and foster a vital and efficient universal mail system."[16]

The final rules aim to strike a balance between the Commission's preference for the transparency of on-the-record communication with the Postal Service and interested parties, and the commenters' desire for a permit-but-disclose approach to ex parte communications. While the final rules do not "permit" ex parte communications, in practice the rules will operate quite similarly to the approach proposed by the commenters. Where applicable, an ex parte communication received by the Commission—in cases other than N, A, and C cases—will be subject only to public disclosure and nothing more. Thus, while ex parte communications will not be permitted or encouraged by the Commission, the Commission will treat ex parte communications in a similar manner as the other agencies mentioned by the commenters.

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[13] *See* Recommendation 2014–4 at 6 ("In formulating policies governing ex parte communications in informal rulemaking proceedings, agencies should consider the following factors: . . . (c) Limitations on agency resources, including staff time, that may affect the ability of agency personnel to accept requests for face-to-face meetings or prepare summaries of such meetings. . . .").

[14] *See* Postal Service Comments at 7 (suggesting the permit-but-disclose approach employed by the DOJ and FCC); MPA Comments at 4 ("A common alternative is to permit ex parte communications but require public disclosure of their substance."); Joint Comments at 8 ("The Commission's proposed rules should be revised . . . to allow the Commission to permit and disclose any *ex parte* communications that it relies on in the context of an informal rulemaking proceeding.").

[15] *See* Postal Service Comments at 6.

[16] Postal Regulatory Commission, Strategic Plan 2012–2016, at 4.

The application of the rules to all cases—other than those exempted by §§ 3008.1(b) through (d)—should alleviate concerns about when the ex parte rules apply. Concerns about "draconian"[17] or "especially punitive"[18] penalties chilling valuable communications should likewise be remedied by the clarification that the penalties will apply only in N, A, and C cases.

By applying the ex parte rules in all case types but only permitting penalties to apply to three specific types of cases, the Commission's final rules aim to eliminate the need for pre-communication evaluation expressed by some commenters of whether a case is a "contested proceeding" or whether a communication "regards the merits" of a case. The ex parte rules' applicability to all case types and communications (aside from those excepted by final §§ 3008.1(b) through (d) and § 3008.2(b)), eliminates uncertainty about the nature of the case and/or communication itself. For example, under the Postal Service's Proposed Rule 3008.2(a), certain terms create uncertainty about the nature of a communication. Specifically, it is unclear how would one determine whether a communication was "intended to affect or influence" or was "capable of affecting or influencing" a Commission decision. The Postal Service's Proposed Rules would also require a determination of what constitutes a "substantive issue in the proceeding." These necessary determinations would create even more uncertainty than the proposed rules. Accordingly, while the Commission supports the goal of eliminating uncertainty, it declines to adopt the revisions set forth in Postal Service Proposed Rules 3008.1 and 3008.2.

B. Commission Reliance on Information Obtained Through Ex Parte Communications

The Postal Service's recommendation that Commission decision-making personnel be permitted to rely on information obtained through ex parte communications is consistent with applicable law. As explained in *Sierra Club,* accepting ex parte communications creates a danger of having one administrative record before the public, and another record before the Commission. *Sierra Club,* 657 F.2d at 401. However, the danger is avoided where the agency relies only on information that is made part of the public record. *Id.* Proposed § 3008.6(c) already contemplates giving participants an opportunity to rebut ex parte communications received and placed on the public record. Reliance on the information received in either an ex parte communication, or any rebuttal, is appropriate to consider when the communications are made part of the public record.

Accordingly, the final rules adopt, in part, the suggestions made in Postal Service Proposed Rule 3008.5(b), regarding Commission reliance on information obtained through ex parte communications. This change is consistent with prevailing agency guidance[19] and with the underlying policy of fairness and transparency, particularly given the provision providing an opportunity for rebuttal of information received via ex parte communication and considered in decision-making. The final rules contain slightly different language than the Postal Service Proposed Rules to enhance clarity and consistency throughout part 3008.

C. When a Matter Is Before the Commission

The Commission acknowledges the comments regarding the definition of when a matter is before the Commission, triggering the application of the ex parte restrictions. The commenters correctly point out that some agencies' ex parte restrictions apply only upon formal notice of commencement of the proceeding. However, as the Public Representative notes, the Commission is differently situated than other administrative agencies, and its current practices go to "considerable effort to accommodate" on-the-record communications. *See* PR Reply Comments at 2–3. Indeed, the Commission generally makes public every matter it considers. The docket system provides ample opportunity for communication on the record.

Under specific circumstances, the APA states that an agency's ex parte communications restrictions may be applied "beginning at such time as the agency may designate," but the prohibitions must apply in cases where "the person responsible for the communication has knowledge that [the case] will be noticed." 5 U.S.C. 557(d)(1)(E). If this requirement were to be applied to proceedings involving periodic reports, such as the Annual Compliance Determination (ACD), the Postal Service contends that all communications would be barred because the filing party always will have knowledge that the case will be noticed. *See* Postal Service Comments at 16.

The final rules address this concern by eliminating the prior knowledge provision where the matter before the Commission is a periodic report, such as the ACD, or the Commission's review required by 39 U.S.C. 3622(d)(3) that should commence later this year. The effect of this change is to not consider these types of matters as being before the Commission until the Commission notices the start of proceeding, unless the Commission issues a notice prior to that time specifically restricting ex parte communications. The matter is no longer before the Commission once the Commission issues its final report or review.

D. Protection of Sensitive Material

The Postal Service expresses concern about the treatment of sensitive or confidential information submitted in ex parte communications. Postal Service Comments at 17–18. The Postal Service suggests revising the proposed rules to require the Commission to advise the disclosing party that the communication must be disclosed and allow an opportunity for an application for non-public treatment to be filed. Postal Service Proposed Rule 3008.6(b).

The Commission's rules located at 39 CFR part 3007 set forth the procedures for the treatment of sensitive material filed on the record in docketed proceedings. Proposed § 3008.6(b) dictates that material submitted not in a docketed proceeding but as part of an ex parte communication must be disclosed in order to be considered by the Commission.

Until disclosure, however, the Commission will treat known sensitive material as confidential, subject to Freedom of Information Act requirements. For example, the Commission may not allow outside persons access to information provided by the Postal Service and identified as exempt from public disclosure. *See* 39 U.S.C. 504(g). The existing statutory safeguards render it unnecessary for the Commission's ex parte rules to further protect sensitive material. Accordingly, the Commission declines to adopt the Postal Service's proposed rule on the protection of sensitive material included in an ex parte communication.

E. Communications Made via Social Media.

The definition of an ex parte communication set forth in proposed § 3008.2(a) includes electronic communications. While most social media interactions are made electronically, social media interactions pose a complex issue requiring further consideration. The Commission takes the Public Representative's suggestion under advisement.

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[17] *See* MPA Comments at 6; Joint Comments at 6–7.

[18] *See* Joint Comments at 9.

[19] *See* Recommendation 2014–4 at 7–8.

F. Recodification of Part 3000

The Commission agrees with the Public Representative that this rulemaking provides an appropriate opportunity to make the numbering of sections in part 3000 consistent with rest of the Commission's rules. As the Public Representative notes, the recodification is not a substantive change to the rules. *See* PR Comments at 14. This change is consistent with this rulemaking's goal of achieving clarity and ease of understanding in the Commission's procedural rules.

V. Changes to the Proposed Rules

The final rules incorporate many of the suggestions identified in the comments. While the suggestions require the structure of the final rules to change from those initially proposed in Order No. 3005, the substance of the rules and their effect on participants remains the same. Differences between the proposed and final rules are described below.

A. Section 3008.1

Proposed § 3008.1 identified the types of Commission matters subject to ex parte restrictions. Listed among those types of matters were nature of postal service proceedings, appeals of post office closings and consolidations, and rate or service complaints. The rule also made applicable, "any other matter in which the Commission, in its discretion, determines that it is appropriate to apply the rules." Order No. 3005 at 12. In order to address commenters' concerns about vagueness and uncertainty of the rules' applicability, the Commission amends proposed § 3008.1 as follows:

1. Section 3008.1(a)

While the proposed rule lists the types of Commission dockets to which the rules apply, the final rules state that the rules of part 3008 apply to all Commission proceedings except for those listed in §§ 3008.1(b) through (d).

2. Sections 3008.1(b) Through (d)

The final rule identifies three types of proceedings to which the rules concerning ex parte communication will not apply. Section 3008.1(b) exempts public inquiry (PI) proceedings undertaken to gather information and which are not intended to result in a binding Commission decision. Section 3008.1(c) exempts international mail (IM) proceedings undertaken pursuant to 39 CFR part 3017. Section 3008.1(d) permits the Commission to identify particular proceedings where the rules will not apply.

B. Section 3008.3

The final rule removes the prior knowledge provision when the matter before the Commission concern matters such as the ACD or § 3622(d)(3) review. These matters will not be considered before the Commission until noticed, or until the Commission issues a prior notice specifically stating that ex parte rules apply.

C. Section 3008.5

Proposed § 3008.5(b) states that "Commission decision-making personnel shall not rely upon any information obtained through ex parte communications." The final rules amend this section by allowing the Commission to rely on information obtained through ex parte communications where the communications are made part of the record and the Commission provides an opportunity for rebuttal.

D. Section 3008.7

The final rule moves proposed §§ 3008.7(a) and (b) to §§ 3008.7(b) and (c), respectively. It replaces § 3008.7(a) with an explanation that the penalties for a violation of the ex parte rules are applicable only to nature of postal service proceedings, appeals of post office closings or consolidations, and rate or service complaints.

E. Part 3000

In accord with the Public Representative's suggestion of renumbering part 3000, the final rules recodify existing rules in conformance with the **Federal Register** Document Drafting Handbook.

Existing part 3000, subpart A includes: § 3000.735–101 Cross-reference to employee ethical conduct standards and financial disclosure regulations; § 3000.735–102 Counseling and advisory services; § 3000.735–103 Financial interests; and § 3000.735–104 Outside employment. These four provisions are renumbered with the following two-digit extensions, respectively: §§ 3000.05, 3000.10, 3000.15, and 3000.20.

Existing part 3000, subpart B is amended as described in Order No. 3005. Additionally, the two provisions are renumbered. Proposed § 3000.735–501 is renumbered as § 3000.50. Proposed § 3000.735–502 is reserved as § 3000.55.

VI. Ordering Paragraphs

It is ordered:

1. Parts 3000 and 3001 of title 39, Code of Federal Regulations, are revised as set forth below the signature of this order, effective 30 days after publication in the **Federal Register**.

2. Part 3008 of title 39, Code of Federal Regulations, is adopted as set forth below the signature of this order, effective 30 days after publication in the **Federal Register**.

3. The Secretary shall arrange for publication of this order in the **Federal Register**.

List of Subjects

39 CFR Part 3000

Conflicts of interests, Ex parte communications.

39 CFR Part 3001

Administrative practice and procedure, Confidential business information, Ex parte communications, Freedom of information, Sunshine Act.

39 CFR Part 3008

Administrative practice and procedure, Ex parte communications.

For the reasons discussed in the preamble, the Commission amends chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3000—STANDARDS OF CONDUCT

■ 1. The authority citation for part 3000 is revised to read as follows:

Authority: 39 U.S.C. 503, 504, 3603; E.O. 12674, 54 FR 15159, 3 CFR,1989 Comp., p. 215, as modified by E.O. 12731, 56 FR 42547, 3 CFR, 1990 Comp., p. 396; 5 CFR parts 2634 and 2635.

Subpart A—General Provisions

§§ 3000.735–101 through 3000.735–104 [Redesignated as §§ 3000.5, 3000.10, 3000.15, 3000.20]

■ 2. Redesignate §§ 3000.735–101 through 3000.735–104 as §§ 3000.5, 3000.10, 3000.15, and 3000.20, respectively.

■ 3. Revise subpart B of part 3000 to read as follows:

Subpart B—Ex Parte Communications

Sec.
3000.50 Ex parte communications prohibited.
3000.55 [Reserved]

Subpart B—Ex Parte Communications

§ 3000.50 Ex parte communications prohibited.

(a) The Commission maintains a written employee policy regarding ex parte communications applicable to all interactions, oral or in writing (including electronic), between Commission decision-making personnel, and the United States Postal Service or public stakeholders in matters before the Commission. It is the responsibility of all Commission personnel to comply with this policy, including the responsibility to inform persons not employed by the Commission of this policy when required. The policy is available for review on the Commission's Web site at *www.prc.gov*.

(b) Additional ex parte communications requirements, applicable to specific docket types, are described in part 3008 of this chapter.

§ 3000.55 [Reserved]

PART 3001—RULES OF PRACTICE AND PROCEDURE

■ 4. The authority citation for part 3001 continues to read as follows:

Authority: 39 U.S.C. 404(d); 503; 504; 3661.

§ 3001.5 [Amended]

■ 5. Amend § 3001.5 by removing and reserving paragraph (o).

§ 3001.7 [Removed and Reserved]

■ 6. Remove and reserve § 3001.7.

■ 7. Add part 3008 to read as follows:

PART 3008—EX PARTE COMMUNICATIONS

Sec.
3008.1 Applicability.
3008.2 Definition of ex parte communications.
3008.3 Definition of a matter before the Commission.
3008.4 Definitions of persons subject to ex parte communication rules.
3008.5 Prohibitions.
3008.6 Required action upon ex parte communication.
3008.7 Penalty for violation of ex parte communication rules.

Authority: 39 U.S.C. 404(d)(5); 503; 504; 3661(c); 3662.

§ 3008.1 Applicability.

(a) The rules in this section are applicable to all Commission proceedings except for the instances identified in paragraphs (b) through (d) of this section.

(b) The rules in this section are not applicable to public inquiry (PI) proceedings, undertaken to gather information and which are not intended to result in a binding Commission decision.

(c) The rules in this section are not applicable to international mail (IM) proceedings undertaken pursuant to part 3017 of this chapter.

(d) The rules in this section are not applicable to specifically identified proceedings upon written directive from the Commission.

§ 3008.2 Definition of ex parte communications.

(a) Subject to the exceptions specified in paragraph (b) of this section, ex parte communications include all communications, oral or written (including electronic), between Commission decision-making personnel, and the Postal Service or public stakeholders regarding matters before the Commission.

(b) Ex parte communications do not include:

(1) Documents filed using the Commission's docketing system;

(2) Communications during the course of Commission meetings or hearings, or other widely publicized events where the Commission provides advance public notice of the event indicating the matter to be discussed, the event is open to all persons participating in the matter before the Commission, and a summary of the event is provided for the record;

(3) Communications during the course of off-the-record technical conferences associated with a matter before the Commission, or the pre-filing conference for nature of service cases required by § 3001.81 of this chapter, where advance public notice of the event is provided indicating the matter to be discussed, and the event is open to all persons participating in the matter before the Commission;

(4) Questions concerning Commission procedures, the status of a matter before the Commission, or the procedural schedule of a pending matter, where these issues are not contested matters before the Commission; and

(5) Communications not material to the matter before the Commission.

§ 3008.3 Definition of a matter before the Commission.

(a) A matter is before the Commission at such time as the Commission may designate, but in no event later than the earlier of the filing of a request to initiate a proceeding or the Commission noticing a proceeding.

(b) A matter is also before the Commission at such time as the person responsible for the communication has knowledge that a request to initiate a proceeding is expected to be filed.

(c) Paragraph (b) of this section does not apply to periodic reviews or reports issued by the Commission, or the 10-year review pursuant to 39 U.S.C. 3622(d)(3).

(d) The following explanations apply:

(1) A matter is no longer before the Commission upon the issuance of the final order or decision in the docketed matter;

(2) A matter is again before the Commission upon the filing of a request for reconsideration. The matter remains before the Commission until resolution of the matter under reconsideration;

(3) A matter is again before the Commission upon the remand of a Commission's final decision or order by an appellate court. The matter remains before the Commission until resolution of the matter under remand; and

(4) The mere potential that a request may be filed does not place a matter before the Commission. An affirmative action announcing, or actively preparing, an actual request with the intent to file within a reasonable period of time must be present.

§ 3008.4 Definitions of persons subject to ex parte communication rules.

(a) Commission decision-making personnel include:

(1) The Commissioners and their staffs;

(2) The General Counsel and staff;

(3) The Director of the Office of Accountability and Compliance and staff;

(4) Contractors, consultants, and others hired by the Commission to assist with the Commission's analysis and decision; and

(5) Any other employee who may reasonably be expected to be involved in the decisional process.

(b) The Postal Service includes all Postal Service employees, contractors, consultants, and others with an interest in a matter before the Commission. Any interaction between the Postal Service and Commission decision-making personnel concerning a matter before the Commission expresses an interest in the matter before the Commission.

(c) Public stakeholders include all other persons not previously described, with an interest in a matter before the Commission. This includes the Commission non-decision-making personnel identified in paragraph (d) of this section. Any interaction between a public stakeholder and Commission decision-making personnel concerning a matter before the Commission expresses an interest in the matter before the Commission.

(d) Commission non-decision-making personnel include:

(1) All Commission personnel other than decision-making personnel;

(2) Commission personnel not participating in the decisional process owing to the prohibitions of § 3001.8 of

this chapter regarding no participation by investigative or prosecuting officers;

(3) The Public Representative and other Commission personnel assigned to represent the interests of the general public pursuant to 39 U.S.C. 505 in the specific case or controversy at issue (regardless of normally assigned duties); and

(4) Contractors, consultants, and others hired by the Commission to provide an independent analysis of issues before the Commission (and Commission employees assigned thereto).

§ 3008.5 Prohibitions.

(a) Ex parte communications between Commission decision-making personnel, and the Postal Service or public stakeholders is prohibited.

(b) Commission decision-making personnel shall not rely upon any information obtained through ex parte communications unless the communications are made part of the record of the proceeding, where an opportunity for rebuttal has been provided, and reliance on the information will not cause undue delay or prejudice to any party.

(c) Paragraph (a) of this section does not constitute authority to withhold information from Congress.

§ 3008.6 Required action upon ex parte communications.

(a) Commission decision-making personnel who receive ex parte communications relevant to the merits of the proceeding shall decline to listen to such communications and explain that the matter is pending for determination. Any recipient thereof shall advise the communicator that the communication will not be considered, and shall promptly and fully inform the Commission in writing of the substance of and the circumstances attending the communication, so that the Commission will be able to take appropriate action.

(b) Commission decision-making personnel who receive, or who make or knowingly cause to be made, ex parte communications prohibited by this part shall promptly place, or cause to be placed, on the public record of the proceeding:

(1) All such written communications;

(2) Memoranda stating the substance of all such oral communications; and

(3) All written responses, and memoranda stating the substance of all oral responses, to the materials described in paragraphs (b)(1) and (2) of this section.

(c) Requests for an opportunity to rebut, on the record, any facts or contentions contained in an ex parte communication which have been placed on the public record of the proceeding pursuant to paragraph (b) of this section may be filed in writing with the Commission. The Commission will grant such requests only where it determines that the dictates of fairness so require. In lieu of actually receiving rebuttal material, the Commission may in its discretion direct that the alleged factual assertion and the proposed rebuttal be disregarded in arriving at a decision.

§ 3008.7 Penalty for violation of ex parte communication rules.

(a) The penalties for violation of ex parte communication rules specified in this section are applicable only to:

(1) Nature of postal service proceedings conducted pursuant to 39 U.S.C. 3661(c);

(2) Appeal of Postal Service decisions to close or consolidate any post office conducted pursuant to 39 U.S.C. 404(d)(5); and

(3) Rate or service complaints conducted pursuant to 39 U.S.C. 3662.

(b) Upon notice of a communication knowingly made or knowingly caused to be made by a participant in violation of § 3008.5(a), the Commission or presiding officer may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the participant to show cause why his/her claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation.

(c) The Commission may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the Commission, consider a violation of § 3008.5(a) sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–15349 Filed 6–29–16; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

Standards of Performance for New Stationary Sources

CFR Correction

In Title 40 of the Code of Federal Regulations, Part 60 (§ 60.1 to end of part 60 sections), revised as of July 1, 2015, make the following corrections:

■ 1. Reinstate the symbol < in the following places:

■ a. On page 85, in § 60.13, paragraph (h)(2)(viii), before the term “30 minutes”;

■ b. On page 667, in § 60.562–1, paragraph (a)(1)(ii) table 3, in row 1., in the second column, after “0.10” and before “5.5”;

■ c. On page 667, in § 60.562–1, paragraph (a)(1)(ii) table 3, in row 3., in the second column, after “5.5” and before “20”;

■ d. On page 706, in § 60.614, (f)(2) table 2, in the first column, in the first two entries, after “H_T”;

■ e. On page 719, in § 60.643, paragraph (a)(1)(ii), after “R”;

■ f. On page 734, in § 60.664, paragraph (f)(2) table 2, in the first column, in the first two entries, after “H_T”;

■ g. On page 1208, in § 60.5410, paragraph (g)(1)(ii), after “R”;

■ h. On page 1222, in § 60.5415, paragraph (g)(1)(ii), after “R”.

■ 2. Reinstate the symbol ≤, in the following places:

■ a. On page 501, in § 60.332, paragraph (a)(4), in the first row of the table, after “N” and before “.015”,

■ b. On pages 1111–1112, in table 1 to subpart KKKK, in the second column, before the number “50” in the first, second, fifth, sixth, and ninth entries;

■ c. On pages 1111–1112, in table 1 to subpart KKKK, in the second column, before the number “850” in the third, seventh, tenth and eleventh entries’

■ d. On pages 1111–1112, in table 1 to subpart KKKK, in the second column, before the number “30” in the twelfth entry.

■ 3. Reinstate the symbol ∃, in the following places:

■ a. On page 649, in § 60.543, paragraph (f)(2)(iv)(I), after “(n” and before “3)”;

■ b. On page 706, in § 60.614, (f)(2) table 2, in the first column, in the third and fourth entries, after “H_T”;

■ c. On page 719, in § 60.643, paragraph (a)(1)(i), after “R”;

■ d. On page 734, in § 60.664, paragraph (f)(2) table 2, in the first column, in the third and fourth entries, after “H_T”;

■ e. On page 1208, in § 60.5410, paragraph (g)(1)(i), after “R”;

■ f. On page 1222, in § 60.5415, paragraph (g)(1)(i), after “R”.

■ 4. Reinstate the symbol > in the following places:

■ a. On pages 1111–1112, in table 1 to subpart KKKK, in the second column, before the number “50” in the third, seventh, tenth, and eleventh entries;

■ b. On pages 1111–1112, in table 1 to subpart KKKK, in the second column, before the number "850" in the fourth and eighth entries;

■ c. On pages 1112, in table 1 to subpart KKKK, in the second column, before the number "30" in the thirteenth entry.

[FR Doc. 2016–15707 Filed 6–29–16; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0183; FRL–9947–45]

Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683–19–8) under 40 CFR 180.910 and 180.930 when used as an inert ingredient (antioxidant/stabilizer) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a maximum concentration of 5% by weight in the formulation and applied to animals at a maximum concentration of 3% by weight in the formulation, respectively. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of these exemptions from the requirement of a tolerance. These regulations eliminate the need to establish a maximum permissible level for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) for these uses.

DATES: This regulation is effective June 30, 2016. Objections and requests for hearings must be received on or before August 29, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0183, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0183 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 29, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0183, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of April 25, 2016 (81 FR 24044) (FRL–9944–86), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10829) by BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932. The petition requested that 40 CFR 180.910 and 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683–19–8) when used as an inert ingredient antioxidant/stabilizer in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 at a maximum concentration of 5% by weight in the formulation; and applied to animals under 40 CFR 180.930 at a maximum concentration of 3% by weight in the formulation. That document referenced a summary of the petition prepared by Lewis & Harrison LLC on behalf of BASF Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.*

There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Pentaerythritol tetrakis 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is not irritating to the eyes and the skin. It is not a dermal sensitizer. In a subchronic study in dogs and a subchronic study in rats, effects were limited to decreases in body weight gain, food consumption, and thyroid weights in rats. No fetal toxicity was reported in developmental toxicity study in the rat. In a developmental toxicity study with mice, incompletely ossified sternebrae in the high-dose group was observed in the absence of maternal toxicity. In a rat 2-generation reproduction study, no adverse effects were observed at doses up to 1,000 milligrams/kilogram/day (mg/kg/day). There was no evidence of carcinogenic potential in a rat chronic toxicity/carcinogenicity study. Specific information on the studies received and the nature of the adverse effects caused by pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate) (CAS Reg. No. 6683–19–8).

Human Health Risk Assessment and Ecological Effects Assessment to Support

A Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient" at pages 10–15 in docket ID number EPA–HQ–OPP–2016–018.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

Based on the results of the available safety studies for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate, the reference dose (RfD) for repeated oral, dermal, and inhalation exposures to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate is 1.35 mg/kg/day. The key study for deriving the RfD is the chronic toxicity study in rats. The NOAEL for in this study is 135 mg/kg/day based on decreases in body weight gain, food consumption, and thyroid weights in males at the LOAEL of 446 mg/kg/day. Applying an uncertainty factor of 100 for extrapolation from animal to human (interspecies variation) and potential variation in sensitivity among members of the human population (intraspecies sensitivity) results in the RfD of 1.35 mg/kg/day. The Food Quality Protection Act (FQPA) (Pub. L. 104–170) safety factor for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate is 1X. The resultant population adjusted dose (PAD) is 1.35 mg/kg/day. The margin of exposure (MOE) for residential exposure is 100 or greater and is based upon the NOAEL derived from the chronic oral toxicity study in rats (135 mg/kg/day) with an assumption of 10% dermal absorption (based on molecular weight and octanol-water partition coefficient) and inhalation toxicity being equivalent oral toxicity.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) in food as follows:

An acute dietary risk assessment was not conducted because no endpoint of concern following a single exposure was identified in the available studies. A chronic dietary exposure assessment was completed and performed using the Dietary Exposure Evaluation Model DEEM–FCID™, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate). In the absence of actual residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model which assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the case of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) EPA made specific adjustments to the dietary exposure assessment to account for the use limitations of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a maximum concentration of % by weight in the pesticide formulation and as an inert ingredient in pesticide formulations applied to animals at a maximum concentration of 3% by weight in the pesticide formulation. Preharvest uses.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Based on the requested use of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), the Agency does not expect non-occupational, non-dietary exposures. However, once approved, there is a potential for residential exposure from use as an inert ingredient in pesticide formulations used in residential settings. These residential exposures could occur by ingestion of materials to which pesticides containing of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate have been applied as well as dermal and inhalation exposures through the use of such products. These residential pesticide exposures are considered short-term and intermediate-term in nature.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) to share a common mechanism of toxicity with any other substances, and pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Fetal susceptibility was not observed in

the developmental toxicity study in mice. In a developmental toxicity study with rats, fetal effects (decreased ossification of the sternebrae) were observed without accompanying maternal toxicity at the high dose group of 500 mg/kg/day. There are no concerns for reproductive toxicity (no effects at up to the limit dose of 1,000 mg/kg/day were observed in a 2-generation reproductive toxicity study in rats).

3. *Conclusion*. EPA has determined that reliable data show the safety of infant and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) includes a subchronic toxicity study, two developmental toxicity studies, a reproductive toxicity study, chronic/carcinogenicity studies, and several mutagenicity studies. No parental or offspring effects were observed in a 2-generation reproductive toxicity study in rats at dose levels up to 500 mg/kg/day, the highest dose tested. In a developmental study in mice, no fetal or maternal effects were observed at doses up to 1,000 mg/kg/day. In a developmental toxicity study in rats no maternal effects were observed at 500 mg/kg/day, the highest dose tested, however, fetal effects were observed, albeit only in the high dose test group of 500 mg/kg/day. Since a clear NOAEL (150 mg/kg/day) for fetal effects was established in this study, no effects are observed in the mice developmental and rat reproductive toxicity study, and the selected point of departure for risk assessment purposes is based on dose levels below which effects are seen in the rat developmental toxicity study, there is no need for an additional UF to account for fetal susceptibility.

ii. There is no indication that pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is a neurotoxic chemical. Although no neurotoxicity studies were available in the database, no clinical signs of neurotoxicity were observed in the available subchronic and chronic studies. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no indication that pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is an immunotoxic chemical. Although no immunotoxicity studies were available in the database, no signs of immunotoxicity were observed in the available studies. Therefore, there is no need for an immunotoxicity study or additional UFs to account for immunotoxicity.

iv. The dietary food exposure assessment utilizes 100% crop treated information for all commodities. By using these screening-level assessments, chronic exposures/risks will not be underestimated. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate).

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) from food and water will utilize 26% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is not expected.

3. *Short-term aggregate risk*. A short-term aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water; and short-term residential exposure. Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) may be used as an inert ingredient in pesticide products that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. The Agency has concluded that the aggregate short-term MOEs for adult and children are above 100. Therefore there is no concern for short-term aggregate risk.

4. *Intermediate-term aggregate risk*. An intermediate-term aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water; and intermediate- term residential exposure. Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) may be used as an inert ingredient in pesticide products that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. The Agency has concluded that the aggregate intermediate-term MOEs for adult and children are above 100. Therefore there is no concern for intermediate term aggregate risk.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in an adequate rodent carcinogenicity studies, pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) in or on any food commodities. EPA is establishing a limitation on the amount of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) that may be used in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals. Those limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide product applied to growing crops and raw agricultural commodities after harvest that contains pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) a concentration of more 5% by weight in the formulation; or any pesticide product applied applied to animals that contains pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) a concentration of more than 3% by weight in the formulation.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683–19–8) when used as an inert ingredient (antioxidant, stabilizer) in pesticide products as follows: under 40 CFR 180.910, at a concentration not to exceed 5% by weight of the formulation in pesticide formulations applied to growing crops and raw agricultural commodities and under 40 CFR 180.930 at a concentration not to exceed 3% by weight of the formulation in pesticide formulations applied to animals.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 13, 2016.

Daniel J. Rosenblatt,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add alphabetically the inert ingredient to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683–19–8).	Not to exceed 5% by weight of the pesticide formulation.	Antioxidant, stabilizer.
* * *	* *	* *

■ 3. In § 180.930, add alphabetically the inert ingredient to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683–19–8).	Not to exceed 3% by weight of the pesticide formulation.	Antioxidant, stabilizer.
* * *	* *	* *

[FR Doc. 2016–15613 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 482, and 483

[CMS–3277–CN]

RIN 0938–AR72

Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on May 4, 2016, entitled "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities."

DATES: This correction is effective July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Kristin Shifflett, (410) 786–4133.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2016–10043 of May 4, 2016 (81 FR 26871), there were technical errors that are identified and corrected in the Correction of Errors section below. The provisions in this correction document are effective as if they had been included in the document published May 4, 2016. Accordingly, the corrections are effective July 5, 2016.

II. Summary of Errors in Regulations Text

On page 26897, at § 416.44(b)(1), we inadvertently omitted a portion of the sentence. We are correcting this sentence to read, ". . . the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served[.]".

On page 26899, at § 482.41(b)(1)(i), we inadvertently omitted a sentence. We are correcting this error by adding a sentence to clarify that outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

On page 26900, at § 483.70(a)(8), we inadvertently specified an incorrect facility type. We are correcting this error to specify the requirements an LTC facility must meet when a sprinkler system is shut down for more than 10 hours.

III. Waiver of Proposed Rulemaking and the 30-Day Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived; however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. In this case, we find that a period for comment and a delay in the effective date of publication are both unnecessary, because this correction notice merely corrects technical and typographical errors in the regulations text and makes no changes in CMS policy. For this reason, we believe we have good cause to waive the APA notice and comment period and delayed effective date.

IV. Correction of Errors

In FR Doc. 2016–10043 of May 4, 2016 (81 FR 26871), make the following corrections:

§ 416.44 [Corrected]

■ 1. On page 26897, in the first column, line 1 (§ 416.44(b)(1)), after the word "Occupancies" insert ", regardless of the number of patients served,".

§ 482.41 [Corrected]

■ 2. On page 26899, in the first column; in § 482.41(b)(1)(i), add a new sentence at the end of the paragraph to read, "Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served."

§ 483.70 [Corrected]

■ 3. On page 26900, in the first column; in § 483.70(a)(8) introductory text, in line 2, the word "ASC" is corrected to read "LTC facility".

Dated: June 22, 2016.

Madhura Valverde,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–15460 Filed 6–29–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Parts 221, 307, 340, and 356

RIN 2133–AB89

Civil Penalties

AGENCY: Maritime Administration (MARAD), Department of Transportation (DOT).

ACTION: Interim final rule.

SUMMARY: This interim final rule updates the maximum civil penalty amounts for violations of statutes and regulations administered by MARAD pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015. This interim final rule amends our regulations to reflect the new, adjusted civil penalty amounts MARAD may assess pursuant for violations of procedures related to the American Fisheries Act, certain regulated transactions involving documented vessels, the Automated Mutual Assistance Vessel Rescue

program (AMVER), and the Defense Production Act.

DATES: This rule is effective August 1, 2016.

ADDRESSES: Office of Chief Counsel, MAR 225, Maritime Administration, 1200 New Jersey Avenue SE., West Building, Second Floor, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: T. Mitchell Hudson, Jr., Office of Chief Counsel, MARAD, telephone (202) 366–9373, email to: *rulemakings.marad@dot.gov,* 1200 New Jersey Ave. SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the Federal Civil Penalties Inflation Adjustment Act Improvement Act (the 2015 Act), Public Law 114–74, Section 701, was signed into law. The purpose of the 2015 Act is to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act requires agencies to make an initial catch up adjustment to the civil monetary penalties they administer through an interim final rule and then to make subsequent annual adjustments for inflation. The amount of increase of any adjustment to a civil penalty pursuant to the 2015 Act is limited to 150 percent of the current penalty. Agencies are required to issue the interim final rule with the initial catch up adjustment by July 1, 2016.

The method of calculating inflationary adjustments in the 2015 Act differs substantially from the methods used in past inflationary adjustment rulemakings conducted pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), Public Law 101–410. Previously, adjustments to civil penalties were conducted under rules that required significant rounding of figures. For example, a penalty increase that was greater than $1,000, but less than or equal to $10,000, would be rounded to the nearest multiple of $1,000. While this allowed penalties to be kept at round numbers, it meant that penalties would often not be increased at all if the inflation factor was not large enough. Furthermore, increases to penalties were capped at 10 percent. Over time, this formula caused penalties to lose value relative to total inflation.

The 2015 Act has removed these rounding rules; now, penalties are simply rounded to the nearest $1. While this creates penalty values that are no longer round numbers, it does ensure that penalties will be increased each year to a figure commensurate with the actual calculated inflation. Furthermore, the 2015 Act "resets" the inflation calculations by excluding prior inflationary adjustments under the Inflation Adjustment Act, which contributed to a decline in the real value of penalty levels. To do this, the 2015 Act requires agencies to identify, for each penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (*i.e.,* originally enacted by Congress) or last adjusted by statute or regulation other than pursuant to the Inflation Adjustment Act.

The Director of the Office of Management and Budget (OMB) provided guidance to agencies in a February 24, 2016 memorandum on how to calculate the initial adjustment required by the 2015 Act.[1] The initial catch up adjustment is based on the change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October in the year the penalty amount was established or last adjusted by Congress and the October 2015 CPI–U. The February 24, 2016 memorandum contains a table with a multiplier for the change in CPI–U from the year the penalty was established or last adjusted to 2015. To arrive at the adjusted penalty, the agency must multiply the penalty amount when it was established or last adjusted by Congress, excluding adjustments under the Inflation Adjustment Act, by the multiplier for the increase in CPI–U from the year the penalty was established or adjusted provided in the February 24, 2016 memorandum. The 2015 Act limits the initial inflationary adjustment to 150 percent of the current penalty. To determine whether the increase in the adjusted penalty is less than 150 percent, the agency must multiply the current penalty by 250 percent. The adjusted penalty is the lesser of either the adjusted penalty based on the multiplier for CPI–U in Table A of the February 24, 2016 memorandum or an amount equal to 250 percent of the current penalty. This interim final rule adjusts the civil penalties for violations of statutes and regulations that MARAD administers consistent with the February 24, 2016 memorandum.

II. Inflationary Adjustments to Penalty Amounts in 46 CFR Part 221

Changes to Civil Penalties for Regulated Transactions Involving Vessel Ownership Transfers and Other Maritime Interests (46 CFR 221.61)

The maximum civil penalties arising under 46 CFR 221.61 have not been updated since they were established, except for inflationary adjustments pursuant to the Inflation Adjustment Act of 1990. The maximum civil penalty for a single violation of any provision under 46 U.S.C. Chapter 313 and all of Subtitle III related MARAD regulations, except section 31329, specified in 31309 of Title 46 of the United States Code was set at $10,000 when the penalty was established by Public Law 100–710, 102 Stat. 4747, enacted in 1988. Likewise, the maximum civil penalty for a single violation of 31329 of Title 46 of the United States Code as it relates to the court sales of documented vessels, specified in 31330 of Title 46 of the United States Code was set at $25,000 when the penalty was established by the same statute, Public Law 100–710, 102 Stat. 4747, enacted in 1988. Lastly, for penalties arising under 46 CFR 221.61, the maximum civil penalty for a single violation of 56101 of Title 46 of the United States Code as it relates to approvals required to transfer a vessel to a noncitizen, specified in 56101(e) of Title 46 United States Code was set at not more than $10,000 when the penalty was established by Public Law 101–225, 103 Stat. 1908, enacted in 1989. Applying the multiplier for the increase in CPI–U for 1988 in Table A of the February 24, 2016 memorandum (1.97869) results in an adjusted civil penalty of $19,787 pursuant to 46 U.S.C. 31309; $49,467 pursuant to 46 U.S.C. 31330. Applying the multiplier for the increase in CPI–U for 1989 (1.89361) results in an adjusted civil penalty of $18,936 pursuant to section 56101(e).

Inflationary Adjustments to Penalty Amounts in 46 CFR Part 307

Changes to Civil Penalties for Failure To File an AMVER Report (46 CFR 307.19)

The maximum civil penalty for a single violation of 50113 of Title 46 of the United States Code related to use and performance reports by operators of vessels as specified in 50113(b) of Title 46 of the United States Code was set at $50.00 per day when the penalty was established by Public Law 84–612, 70 Stat. 332, enacted in 1956. This civil penalty has not been updated since it was established. Applying the multiplier for the increase in CPI–U for 1956 in Table A of the February 24,

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[1] Memorandum from the Director of OMB to Heads of Executive Departments and Agencies, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Feb. 24, 2016), *available at www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-06.pdf.*

2016 memorandum (8.64865) would result in an adjusted civil penalty of $432.433, which is more than the limitation on inflationary adjustments of 150 percent, accordingly the adjusted civil penalty is $125.00, which is 150 percent of the previously penalty amount not counting updates made under the Inflation Adjustment Act.

Inflationary Adjustments to Penalty Amounts in 46 CFR Part 340

Changes to Civil Penalties for Violating Procedures for the Use and Allocation of Shipping Services, Port Facilities and Services for National Security and National Defense Operations (46 CFR 340.9)

The maximum civil penalty for a single violation of 4501 of Title 50 of the United States Code, specified in 4513 of Title 50 of the United States Code, at 46 CFR 340.9, was set at not more than $10,000 when the penalty was established by the Defense Production Act, 64 Stat. 799, enacted in 1950. This civil penalty has not been updated since it was established. Applying the multiplier for the increase in CPI–U for 1950 in Table A of the February 24, 2016 memorandum (9.66821) would result in an adjusted civil penalty of $96682.1, which is above the 150 percent limit for inflationary adjustments, so the adjusted civil penalty is $25,000, which is 150 percent of the previous penalty amount not counting updates under the Inflation Adjustment Act.

Inflationary Adjustments to Penalty Amounts in 46 CFR Part 356

Changes to Civil Penalties for Violations in Applying For or Renewing a Vessel's Fishery Endorsement (46 CFR 356.49)

The maximum civil penalty for a single violation of 12151 of Title 46 of the United States Code for engaging in fishing operations as defined in section 3 of the Magnuson-Stevens Fishery Conservation and Management Act, within the Exclusive Economic Zone, specified in 12151(c) of Title 46 of the United States Code, and at 46 CFR 356.49, was set at $100,000.00 for each day such vessel engaged in fishing when the penalty was established by Public Law 105–277, 112 Stat. 2681–620, enacted in 1998. This civil penalty has not been updated since it was established. Applying the multiplier for the increase in CPI–U for 1998 in Table A of the February 24, 2016 memorandum (1.45023) results in an adjusted civil penalty of $145,023.

III. Dispensing With Notice and Public Comment

MARAD is promulgating this interim final rule to ensure that the amount of civil penalties contained in 46 CFR 221.61, 307.19, 340.9 and 356.49—reflect the statutorily mandated ranges as adjusted for inflation. Pursuant to the 2015 Act, MARAD is required to promulgate a "catch-up adjustment" through an interim final rule. Pursuant to the 2015 Act and 5 U.S.C. 553(b)(3)(B), MARAD finds that good cause exists for immediate implementation of this interim final rule without prior notice and comment because it would be impracticable to delay publication of this rule for notice and comment and because public comment is unnecessary. By operation of the Act, MARAD must publish the catch-up adjustment by interim final rule by July 1, 2016. Additionally, the 2015 Act provides a clear formula for adjustment of the civil penalties, leaving the agency little room for discretion. Furthermore, the increases in MARAD's civil penalty authority authorized by 46 U.S.C. 12151(c), 31309, 31330, 50113(b), 56101(e) and 50 U.S.C. 4513 are already in effect and the amendments merely update the relevant regulations to reflect the new statutory civil penalty. For these reasons, MARAD finds that notice and comment would be impracticable and is unnecessary in this situation.

IV. Rulemaking Analyses and Notices

Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

MARAD has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed under Executive Order 12866 or Executive Order 13563. This action is limited to the adoption of adjustments of civil penalties under statutes that the agency enforces, and has been determined to be not "significant" under the Department of Transportation's regulatory policies and procedures and the policies of the Office of Management and Budget. Because this rulemaking does not change the number of entities that are subject to civil penalties, the impacts are limited. Furthermore, excluding the penalties in 46 CFR 221.61, 307.19, 340.9 and 356.49 for violating certain long standing procedures, this final rule does not establish civil penalty amounts that MARAD is required to seek.

We also do not expect the increase in the civil penalty amount in any of these regulations to be economically significant. Over the last five years, MARAD has not collected any civil penalties under these regulations. Increasing the current civil penalty amount by 150 percent would not result in an annual effect on the economy of $100 million or more.

Regulatory Flexibility Act

We have also considered the impacts of this notice under the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact on a substantial number of small entities. Since this regulation does not establish a penalty amount that MARAD is required to seek, except for the long standing civil penalties set forth in 46 CFR 221.61, 307.19, 340.9 and 356.49, this rule will not have a significant economic impact on small businesses. Additionally, over the last five years, MARAD has not collected any civil penalties under these regulations. Accordingly, increasingly the civil penalty amount is unlikely to have any economic impact on any small businesses.

In addition, MARAD has determined the RFA does not apply to this rulemaking. The 2015 Inflation Act requires MARAD to publish an interim final rule and does not require MARAD to complete notice and comment procedures under the APA. The Small Business Administration's *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (2012), provides that:

> If, under the APA or any rule of general applicability governing federal grants to state and local governments, the agency is required to publish a general notice of proposed rulemaking (NPRM), the RFA must be considered [citing 5 U.S.C. 604(a)]. . . . If an NPRM is not required, the RFA does not apply.

Therefore, because the 2015 Inflation Act does not require an NPRM for this rulemaking, the RFA does not apply.

Executive Order 13132 (Federalism)

Executive Order 13132 requires MARAD to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, the agency may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, the agency consults with State and local governments, or the agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule only updates existing penalties, pursuant to statute. MARAD has not collected any civil penalties under these regulations within the last five years and if it were to assess penalties, due to the amounts involved, it would not have a substantial direct effect on a State. Thus, the requirements of Section 6 of the Executive Order do not apply.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires agencies to prepare a written assessment of the cost, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. Because this rule will not have a $100 million effect, no Unfunded Mandates assessment will be prepared.

Executive Order 12778 (Civil Justice Reform)

This rule does not have a retroactive or preemptive effect. Judicial review of a rule based on this proposal may be obtained pursuant to 5 U.S.C. 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, we state that there are no requirements for information collection associated with this rulemaking action.

Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov.*

List of Subjects

46 CFR Part 221

Regulated Transactions Involving Documented Vessels and Other Maritime Interests.

46 CFR Part 307

Establishment of Mandatory Position Reporting System for Vessels.

46 CFR Part 340

Priority Use and Allocation of Shipping Services, Containers and Chassis, and Port Facilities and Services for National Security and National Defense Related Operations.

46 CFR Part 356

Requirements for Vessels of 100 Feet or Greater in Registered Length to Obtain a Fishery Endorsement to the Vessel's Documentation.

In consideration of the foregoing, 46 CFR parts 221, 307, 340, and 356 are amended as set forth below.

PART 221—REGULATED TRANSACTIONS INVOLVING DOCUMENTED VESSELS AND OTHER MARITIME INTERESTS

■ 1. The authority citation for 46 CFR part 221 is revised to read as follows:

Authority: 46 U.S.C. chs. 301, 313, and 561; Pub. L. 114–74; 49 CFR 1.93.

■ 2. Section 221.61 is revised to read as follows:

§ 221.61 Compliance.

(a) This subpart describes procedures for the administration of civil penalties that the Maritime Administration may assess under 46 U.S.C. 31309, 31330 and 56101, pursuant to 49 U.S.C. 336.

(b) Pursuant to 46 U.S.C. 31309, a general penalty of not more than $19,787 may be assessed for each violation of chapter 313 or 46 U.S.C. subtitle III administered by the Maritime Administration, and the regulations in this part that are promulgated thereunder, except that a person violating 46 U.S.C. 31329 and the regulations promulgated thereunder is liable for a civil penalty of not more than $49,467 for each violation. A person that charters, sells, transfers or mortgages a vessel, or an interest therein, in violation of 46 U.S.C. 56101(e) is liable for a civil penalty of not more than $18,936 for each violation.

PART 307—ESTABLISHMENT OF MANDATORY POSITION REPORTING SYSTEM FOR VESSELS

■ 3. The authority citation for 46 CFR part 307 is revised to read as follows:

Authority: Pub. L. 109–304; 46 U.S.C. 50113; Pub. L. 114–74; 49 CFR 1.93.

■ 4. Section 307.19 is revised to read as follows:

§ 307.19 Penalties.

The owner or operator of a vessel in the waterborne foreign commerce of the United States is subject to a penalty of $125.00 for each day of failure to file an AMVER report required by this part. Such penalty shall constitute a lien upon the vessel, and such vessel may be libeled in the district court of the United States in which the vessel may be found.

PART 340—PRIORITY USE AND ALLOCATION OF SHIPPING SERVICES, CONTAINERS AND CHASSIS, AND PORT FACILITIES AND SERVICES FOR NATIONAL SECURITY AND NATIONAL DEFENSE RELATED OPERATIONS

■ 5. The authority citation for 46 CFR part 340 is revised to read as follows:

Authority: 50 U.S.C. 4501 *et seq.* ("The Defense Production Act"); Executive Order 13603 (77 FR 16651); Executive Order 12656 (53 FR 47491); Pub. L. 114–74; 49 CFR 1.45; 49 CFR 1.93(l).

■ 6. Section 340.9 is revised to read as follows:

§ 340.9 Compliance.

Pursuant 50 U.S.C. 4513 any person who willfully performs any act prohibited, or willfully fails to perform any act required, by the provisions of this regulation shall, upon conviction, be fined not more than $25,000 or imprisoned for not more than one year, or both.

PART 356—REQUIREMENTS FOR VESSELS OF 100 FEET OR GREATER IN REGISTERED LENGTH TO OBTAIN A FISHERY ENDORSEMENT TO THE VESSEL'S DOCUMENTATION

■ 6. The authority citation for 46 CFR part 356 is revised to read as follows:

Authority: 46 U.S.C. 12102; 46 U.S.C. 12151; 46 U.S.C. 31322; Pub. L. 105–277, division C, title II, subtitle I, section 203 (46 U.S.C. 12102 note), section 210(e), and section 213(g), 112 Stat. 2681; Pub. L. 107–20, section 2202, 115 Stat. 168–170; Pub. L. 114–74; 49 CFR 1.93.

■ 7. In § 356.49, revise paragraph (b) to read as follows:

§ Penalties.

* * * * *

(b) A fine of up to $145,023 may be assessed against the vessel owner for each day in which such vessel has engaged in fishing (as such term is defined in section 3 of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802) within the exclusive economic zone of the United States; and

* * * * *

Dated: June 27, 2016.

By Order of the Maritime Administrator.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2016–15566 Filed 6–29–16; 8:45 am]

BILLING CODE 4910–81–P

FEDERAL MARITIME COMMISSION

46 CFR Part 506

[Docket No. 16–13]

RIN 3072–AC63

Inflation Adjustment of Civil Monetary Penalties

AGENCY: Federal Maritime Commission.

ACTION: Interim final rule.

SUMMARY: This rule implements the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act) (Sec. 701 of Pub. L. 11–74). The rule adjusts the maximum amount of each statutory civil penalty subject to Federal Maritime Commission (Commission) jurisdiction for inflation, in accordance with the requirements of that Act. The 2015 Act requires that agencies publish a catch-up adjustment in the penalties in an interim rule by July 1, 2016, and that agencies adjust penalties yearly thereafter.

DATES: This rule is effective on August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Tyler Wood, General Counsel, Federal Maritime Commission, 800 North Capitol Street NW., Room 1018, Washington, DC 20573, (202) 523–5740.

SUPPLEMENTARY INFORMATION: This rule implements the 2015 Act, which became effective on November 2, 2015. The 2015 Act further amends the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), Public Law 101–410, 104 Stat. 890 (codified as amended at 28 U.S.C. 2461 note), in order to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The Debt Collection Improvement Act of 1996 (DCIA), Public Law 104–134, Title III, 31001(s)(1), 110 Stat. 1321–373, originally amended the FCPIAA and required the head of each executive agency to adopt regulations that adjust the maximum civil monetary penalties (CMPs) assessable under its agency's jurisdiction at least every four years to ensure that they continued to maintain their deterrent value.[1] In accordance with the DCIA, the Commission established Part 506 in 1996 and adjusted its penalties.[2] The Commission further adjusted its civil penalty amounts in 2000, 2009, and 2014.[3]

The 2015 Act requires that agencies publish a catch-up adjustment in the penalties in an interim rule by July 1, 2016, to become effective no later than August 1, 2016. Following the catch-up adjustment, the 2015 Act requires agencies to adjust CMPs under their jurisdiction annually beginning in 2017 based on changes in the consumer price index using data from October in the previous calendar year.

In order to catch-up CMPs, the 2015 Act requires agencies to identify the year the civil penalty was established or last adjusted by statute or regulation *other than* pursuant to the FCPIAA.[4] Catch-up adjustments are based on the percent change between the Consumer Price Index for all Urban Consumers (CPI–U)[5] for the month of October of the year in which the CMP was established or adjusted (other than through Inflation Adjustment Act adjustments), and the October 2015 CPI–U. In accordance with the 2015 Act, the Office of Management and Budget (OMB) has issued guidance to agencies on implementing the catch-up adjustments and provided multipliers for agencies to use depending on the year a civil penalty was established or adjusted (other than inflation adjustments). Agencies look at the multiplier corresponding to that year in a table provided by OMB.[6] Next, agencies multiply the amount of the penalty (not adjusted for inflation) by the amount in the table.[7] Under the 2015 Act, however, the catch-up increase cannot exceed 150% of the amount that was effective on November 2, 2015.[8]

For example, Section 13 of the Shipping Act of 1984 (1984 Act), 46 U.S.C. 41107, imposes a maximum $45,000 penalty for a knowing and willful violation of the 1984 Act.[9] The penalty was established in 1984 for an amount of $25,000 and has only been adjusted pursuant to the FCPIAA since then. As a result, the Commission multiplied $25,000 by 2.25867 (the multiplier provided by OMB for 1984) to obtain an adjusted CMP of $55,467.

The last time the Commission adjusted its CMP *not* pursuant to FCPIAA varies depending on the penalty.[10] Accordingly, the Commission has looked at the multiplier in the table OMB provided to determine the appropriate adjustment for its civil penalties. In order to provide some clarity, the table below shows the non-inflation-adjusted penalty, the year it was established or adjusted (other than under the FCPIAA), the multiplier provided by OMB, and the result of applying the multiplier (rounded to the nearest dollar per the statute). The table also shows 250% of the amount of the penalty in November 2015 (2015 Act Cap). The new adjusted maximum penalty is the lesser of (1) the amount using the multiplier and (2) 250% of the amount of the penalty in November 2015.

U.S.C. Section	Non-inflation-adjusted penalty	Year	Multiplier	Multiplier result	2015 Act cap (250% of 11/2/15 Amount)	New adjusted maximum penalty amount
46 U.S.C. 42304	1,000,000	1988	1.97869	1,978,690	4,000,000	1,978,690

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[1] Increased CMPs are applicable only to violations occurring after the increase takes effect.

[2] 61 FR 52704 (Oct. 8, 1996).

[3] 65 FR 49741 (Aug. 15, 2000); 74 FR 38114 (July 28, 2009); 79 FR 37662 (July 2, 2014).

[4] 5(b)(2); Memorandum for the Heads of Executive Departments and Agencies for the Implementation of the Federal Civil Penalties Inflation Adjustment Act, M–16–06, at 4, February 24, 2016 (OMB Guidance Memo).

[5] 3(3).

[6] *Id.*

[7] *Id.* The amount of the catch-up penalty cannot exceed 250% of the amount that was effective on November 2, 2015 which would be $112,500 for a violation of Section 13.

[8] The 150 percent limitation in the 2015 Act is on the amount of the increase. The actual adjusted penalty levels, however are capped at 250 percent of the levels in effect on November 2, 2015. M–16–06, OMB guidance memo, at 3; also at 5(b)(2)(C).

[9] The Commission last adjusted its civil penalties pursuant to FCPIAA in 2014.

[10] Current CMPs at the Commission have been effective since July 11, 2014. 79 FR 37662 (July 2, 2014).

U.S.C. Section	Non-inflation-adjusted penalty	Year	Multiplier	Multiplier result	2015 Act cap (250% of 11/2/15 Amount)	New adjusted maximum penalty amount
46 U.S.C. 41107(a)	25,000	1984	2.25867	56,467	112,500	56,467
46 U.S.C. 41107(b)	5,000	1984	2.25867	11,293	22,500	11,293
46 U.S.C. 41108(b)	50,000	1984	2.25867	112,934	200,000	112,934
46 U.S.C. 42104	5,000	1990	1.78156	8,908	22,500	8,908
46 U.S.C. 42106	1,000,000	1990	1.78156	1,781,560	4,000,000	1,781,560
46 U.S.C. 42108	50,000	1990	1.78156	89,078	200,000	89,078
46 U.S.C. 44102	5,000	1966	7.22912	36,146	22,500	22,500
	200			1,446	750	750
46 U.S.C. 44103	5,000	1966	7.22912	36,146	22,500	22,500
	200			1,446	750	750
31 U.S.C. 3802(a)(1)	5,000	1986	2.15628	10,781	22,500	10,781
31 U.S.C. 3802(a)(2)	5,000	1986	2.15628	10,781	22,500	10,781

The new formula may result in a lower penalty than the current penalty. The catch-up penalty for 46 U.S.C. 42104 of $8,908, is actually lower than the current penalty of $9,000. This results from two things: (1) the lack of a specific penalty for a violation of 46 U.S.C. 42104 until 1990; and (2) using a multiplier based on the year the penalty was established or modified that excludes adjustments due to the FCPIAA. The later a penalty was established that excludes adjustments due to the FCPIAA, the smaller the multiplier. In this example, the latest penalty amount that excludes adjustments due to the FCPIAA for violating 46 U.S.C. 42104 is $5,000, established in 1990. The $5,000 penalty, therefore, is multiplied by 1.78156 percent to get the adjusted penalty of $8,908.

In contrast, the oldest non-FCPIAA penalty for violating 46 U.S.C. 44103 was established in 1966 in the amount of $5,000. Accordingly, using the required table, such amount is multiplied by 7.22912 percent to get the adjusted penalty of $22,500.

The 2015 Act also requires that agencies round up any increases in civil monetary penalties by a dollar regardless of the amount of the penalty, which differs from the prior rounding system that was based on the amount of a penalty. The penalty in 46 U.S.C. 42104 was between $1,000 and $10,000, and increases were therefore rounded to the nearest $1,000 (often the next highest $1,000), resulting in higher adjusted amounts.[11]

The Commission is also making a number of changes to other sections in part 506 to reflect the amendments made by the 2015 Act, including the frequency and calculation of future increases, how increases are rounded, and when they apply.

This interim final rule is issued without prior public notice or opportunity for public comment. Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), a final rule may be issued without notice and comment if the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. In this instance, the Commission finds, for good cause, that solicitation of public comment on this final rule is unnecessary and impractical.

Specifically, Congress has mandated that the agency make the catch-up inflation adjustments through an interim final rule, and agencies are not required to conduct notice and comment prior to promulgation. The Commission, under the FCPIAA as amended by the 2015 Act, is required to make the adjustment to the civil monetary penalties according to a formula specified in the statute. The regulation requires ministerial, technical computations that are noncontroversial.

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because the Commission has determined that notice and comment are not required under the APA for this rulemaking, the requirements of the RFA do not apply and no regulatory flexibility analysis was prepared.

The rule does not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995, as amended. Therefore, Office of Management and Budget review is not required.

This regulatory action is not a major rule as defined under 5 U.S.C. 804(2).

List of Subjects in 46 CFR Part 506

Administrative practice and procedure, Penalties.

For the reasons stated in the preamble, Part 506 of title 46 of the Code of Federal Regulations is amended as follows:

PART 506—CIVIL MONETARY PENALTY INFLATION ADJUSTMENT

■ 1. The authority citation for part 506 continues to read as follows:

Authority: 28 U.S.C. 2461.

■ 2. Revise § 506.1 to read as follows:

§ 506.1 Scope and purpose.

The purpose of this part is to establish a mechanism for the regular adjustment for inflation of monetary penalties and to adjust such penalties in conformity with the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2641 note) as originally amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, April 26, 1996, and currently amended by the Federal Civil Penalties Inflation Act Adjustment Improvements Act of 2015, Public Law 114–74, in order to maintain the deterrent effect of civil monetary penalties and to promote compliance with the law.

■ 3. In § 506.3, revise the introductory text to read as follows:

§ 506.3 Civil monetary penalty inflation adjustment.

The Commission shall, not later than August 1, 2016, and at least every year thereafter—

* * * * *

■ 4. Revise § 506.4 to read as follows:

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[11] *See* 46 CFR 506.4.

§ 506.4 Cost of living adjustments of civil monetary penalties.

(a) The inflation adjustment under § 506.3 will initially be determined by increasing the maximum civil monetary penalty for each civil monetary penalty by the initial cost-of-living adjustment. The inflation adjustment will subsequently be determined by increasing the maximum civil monetary penalty for each civil monetary penalty by the cost-of-living adjustment. Any increase determined under this section shall be rounded to the nearest multiple of $1.

(b) *Inflation adjustment.* For purposes of paragraph (a) of this section, the term 'cost-of-living adjustment' means the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of October preceding the adjustment exceeds the Consumer Price Index for the month of October 1 year before the month of October preceding the adjustment.

(c) *Initial adjustment.* For purposes of paragraph (a) of this section, the term 'initial cost-of-living-adjustment' means the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of October, 2015 exceeds the Consumer Price Index for the month of October of the calendar year during which the amount of such civil monetary penalty was established or adjusted under a provision of law of civil monetary penalty. The initial cost-of-living adjustment may not exceed 150 percent of such penalty on November 2, 2015, the date of the enactment of the Federal Civil Penalties Inflation Act Adjustment Improvements Act of 2015.

(d) *Inflation adjustment.* Maximum Civil Monetary Penalties within the jurisdiction of the Federal Maritime Commission are adjusted for inflation as follows:

United States Code Citation	Civil monetary penalty description	Maximum penalty amount prior to August 1, 2016	New adjusted maximum penalty amount as of August 1, 2016
46 U.S.C. 42304	Adverse impact on U.S. carriers by foreign shipping practices.	1,600,000	1,978,690
46 U.S.C. 41107(a)	Knowing and Willful violation/Shipping Act of 1984, or Commission regulation or order.	45,000	56,467
46 U.S.C. 41107(b)	Violation of Shipping Act of 1984, Commission regulation or order, not knowing and willful.	9,000	11,293
46 U.S.C. 41108(b)	Operating in foreign commerce after tariff suspension	80,000	112,934
46 U.S.C. 42104	Failure to provide required reports, etc./Merchant Marine Act of 1920.	9,000	8,908
46 U.S.C. 42106	Adverse shipping conditions/Merchant Marine Act of 1920.	1,600,000	1,781,560
46 U.S.C. 42108	Operating after tariff or service contract suspension/Merchant Marine Act of 1920.	80,000	89,078
46 U.S.C. 44102	Failure to establish financial responsibility for non-performance of transportation.	9,000 300	22,500 750
46 U.S.C. 44103	Failure to establish financial responsibility for death or injury.	9,000 300	22,500 750
31 U.S.C. 3802(a)(1)	Program Fraud Civil Remedies Act/makes false claim	9,000	10,781
31 U.S.C. 3802(a)(2)	Program Fraud Civil Remedies Act/giving false statement.	9,000	10,781

■ 5. Revise § 506.5 to read as follows:

§ 506.5 Application of increase to violations.

Any adjustment in a civil monetary penalty under this part shall apply only to civil monetary penalties, including those whose associated violation predated such increase, which are assessed after the date the adjustment takes effect.

By the Commission.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–15569 Filed 6–29–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[DA 16–644]

Adjustment of Civil Monetary Penalties To Reflect Inflation

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Inflation Adjustment Act) requires the Federal Communications Commission to amend its forfeiture penalty rules for inflation.

DATES: This rule is effective August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Donna Cyrus, Enforcement Bureau, 202–418–7325.

SUPPLEMENTARY INFORMATION: On June 9, 2016, the Enforcement Bureau of the Federal Communications Commission adopted and released an order on delegated authority, DA 16–644, which adjusts the Commission's forfeiture penalties for inflation. On November 2, 2015, the President signed into law the Bipartisan Budget Act of 2015, which included, as Section 701 thereto, the 2015 Inflation Adjustment Act, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), to improve the effectiveness of civil monetary penalties and maintain their deterrent effect. Under the act, federal agencies, including the Federal Communications Commission, must issue an interim final rulemaking and publish interim final rules by July 1, 2016, which will take effect by August 1, 2016. According to the 2015 Inflation Adjustment Act, the initial inflation adjustment will be the percentage by which the Consumer Price Index (CPI) for the month of October 2015 exceeds the CPI for the month of October of the calendar year during which the civil monetary penalty "was established or adjusted under a provision of law other than this Act." The 2015 Inflation Adjustment Act requires the Director of the Office of Management and Budget (OMB) to issue, guidance to agencies on implementing the Act. OMB issued that guidance on February 24, 2016, and this Order follows that guidance. Pursuant to the 2015 Inflation Adjustment Act, we update the civil monetary penalties set forth in the Communications Act of 1934, as amended (Communications Act or Act), to reflect an "inflation adjustment" that derives from the "cost-of-living adjustment." The cost-of-living adjustment reflects the total inflation that has taken place in the years since the penalties were last set or adjusted by statute or rule.

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

The Commission will not send a copy of this Order per the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the rules are amended only to account for inflation and do not substantially affect the rights or obligations of non-agency parties.

List of Subjects

Administrative practice and procedure, Penalties.

Federal Communications Commission.

Lisa S. Gelb,

Chief of Staff, Enforcement Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 part 1 as follows:

PART 1—PRACTICE AND PROCEDURE

Subpart A—General Rules of Practice and Procedure

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 79 *et seq.*, 47 U.S.C. 151, 154(i) and (j), 155, 157, 225, 227, 303(r), and 309.

■ 2. Section 1.80 is amended by revising the table following paragraph (b)(8) "Section III. Non-Section 503 Forfeitures That Are Affected by the Downward Adjustment Factors" and revising paragraph (b)(9) to read as follows:

§ 1.80 Forfeiture proceedings.

* * * * *

Section III. Non-Section 503 Forfeitures That Are Affected by the Downward Adjustment Factors

* * * * *

Violation	Statutory amount ($)
Sec. 202(c) Common Carrier Discrimination	$11,362, $568/day.
Sec. 203(e) Common Carrier Tariffs	11,362, 568/day.
Sec. 205(b) Common Carrier Prescriptions	22,723.
Sec. 214(d) Common Carrier Line Extensions	2,272/day.
Sec. 219(b) Common Carrier Reports	2,272/day.
Sec. 220(d) Common Carrier Records & Accounts	11,362/day.
Sec. 223(b) Dial-a-Porn	117,742.
Sec. 227(e) Caller Identification	10,874/violation. 32,622/day for each day of continuing violation, up to 1,087,450 for any single act or failure to act.
Sec. 364(a) Forfeitures (Ships)	9,468/day (owner).
Sec. 364(b) Forfeitures (Ships)	1,894 (vessel master).
Sec. 386(a) Forfeitures (Ships)	9,468/day (owner).
Sec. 386(b) Forfeitures (Ships)	1,894 (vessel master).
Sec. 634 Cable EEO	839.

(9) *Inflation adjustments to the maximum forfeiture amount.*

(i) Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Inflation Adjustment Act), Public Law 114–74 (129 Stat. 599–600), which amends the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990, Public Law 101–410 (104 Stat. 890; 28 U.S.C. 2461 note), the statutory maximum amount of a forfeiture penalty assessed under this section shall be adjusted for inflation with an initial "catch-up" adjustment through an interim final rulemaking and interim final rules published by July 1, 2016, to take effect by August 1, 2016. Subsequent annual adjustments shall be published by January 15 each year. Catch-up adjustments will be based on the 'cost-of-living adjustment' (CPI), which is the percentage (if any) by which the CPI for October in the year of the previous adjustment exceeds the CPI for October 2015. Annual inflation adjustments will be based on the percentage (if any) by which the CPI for October preceding the date of the adjustment exceeds the prior year's CPI for October. The Office of Management and Budget has provided "Table A: 2016 Civil Monetary Penalty Catch-Up Adjustment Multiplier by Calendar Year" (Table A) to determine the civil monetary penalty catch-up adjustment multiplier by calendar year. The Catch-up adjustment is determined by

(A) Identifying from Table A, column A the latest year the penalty level or penalty range was established or last adjusted by statute or regulation (other than pursuant to the Inflation Adjustment Act), and from column B, identifying the corresponding multiplier to adjust the penalty level or range for inflation;

(B) Multiplying the corresponding amount from column B by the amount of the maximum penalty level or the range of minimum and maximum penalties as most recently established or adjusted by statute or regulation (other than pursuant to the Inflation Adjustment Act before November 2, 2015);

(C) Rounding to the nearest dollar; and

(D) Comparing the new amount or range of the penalty with the amount or range in the prior year to ensure the maximum increase is not more than 150 percent of the most recent levels.

(ii) The application of the inflation adjustments required by the 2015 Inflation Adjustment Act, 28 U.S.C. 2461 note, results in the following adjusted statutory maximum forfeitures authorized by the Communications Act:

U.S. Code citation	Maximum penalty after 2015 inflation adjustment act adjustment ($)
47 U.S.C. 202(c)	$11,362 568
47 U.S.C. 203(e)	11,362 568
47 U.S.C. 205(b)	22,723
47 U.S.C. 214(d)	2,272
47 U.S.C. 219(b)	2,272
47 U.S.C. 220(d)	11,362
47 U.S.C. 223(b)	117,742
47 U.S.C. 227(e)	10,874 32,622 1,087,450
47 U.S.C. 362(a)	9,468
47 U.S.C. 362(b)	1,894
47 U.S.C. 386(a)	9,468
47 U.S.C. 386(b)	1,894
47 U.S.C. 503(b)(2)(A)	47,340 473,402
47 U.S.C. 503(b)(2)(B)	189,361 1,893,610
47 U.S.C. 503(b)(2)(C)	383,038 3,535,740
47 U.S.C. 503(b)(2)(D)	18,936 142,021 108,745
47 U.S.C. 503(b)(2)(F)	1,087,450 1,875
47 U.S.C. 507(a)	....
47 U.S.C. 507(b)	275
47 U.S.C. 554	839

* * * * * * *

[FR Doc. 2016–14801 Filed 6–29–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 202

[Docket DARS–2016–0008]

RIN 0750–AI89

Defense Federal Acquisition Regulation Supplement: Deletion of Supplemental Coverage for the Definition of "Simplified Acquisition Threshold" (DFARS Case 2016–D007)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to delete the supplemental coverage for the definition "simplified acquisition threshold." Federal Acquisition Regulation (FAR) final rule 2015–020 added to the FAR the simplified acquisition threshold for contracts to be awarded and performed, or purchases to be made, outside the United States in support of a humanitarian or peacekeeping operation.

DATES: *Effective* June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Defense Acquisition Regulations System, Attn: Ms. Julie Hammond, OUSD (AT&L) DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is amending the DFARS to delete the supplemental definition for "simplified acquisition threshold" with regard to humanitarian or peacekeeping operations at DFARS part 202. This supplemental definition was included in DFARS when there was no existing coverage in the FAR. The simplified acquisition threshold for humanitarian or peacekeeping operations has been added to the FAR under final rule 2015–020. There is no need to duplicate the definition in the DFARS; therefore, this rule removes the supplemental definition at DFARS part 202.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

41 U.S.C. 1707, Publication of Proposed Regulations, is the statute that applies to the publication of the Federal Acquisition Regulation (FAR). Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because the DFARS change to remove a definition that is being elevated to the FAR will not have any cost or administrative impact on contractors or offerors.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30.

IV. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the

Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 202

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 202 is amended as follows:

PART 202—DEFINITIONS OF WORDS AND TERMS

■ 1. The authority citation for 48 CFR part 202 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

202.101 [Amended]

■ 2. Amend section 202.101 by removing the definition of "Simplified acquisition threshold".

[FR Doc. 2016–15236 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212 and 252

[Docket DARS–2016–0015]

RIN 0750–AI93

Defense Federal Acquisition Regulation Supplement: Pilot Program on Acquisition of Military Purpose Nondevelopmental Items (DFARS Case 2016–D014)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that changes the criteria for the pilot program on acquisition of military purpose nondevelopmental items.

DATES: *Effective* June 30, 2016.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before August 29, 2016 to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D014, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "DFARS Case 2016–D014" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "DFARS Case 2016–D014." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "DFARS Case 2016–D014" on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D014 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Mr. Dustin Pitsch, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Dustin Pitsch, telephone 571–372–6090.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule revises the DFARS to implement section 892 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92). Section 892 amends section 866 of the NDAA for FY 2011 (Pub. L. 111–383) to modify the criteria for use of the pilot program on acquisition of military purpose nondevelopmental items. Section 892 removes the requirements under the program for the use of competitive procedures and for awards to be made to nontraditional defense contractors. Section 892 also increases the threshold for use of the pilot program to contracts up to $100 million.

Section 866 was implemented in DFARS rule 2011–D034, Pilot Program on Acquisition of Military Purpose Nondevelopmental Items (77 FR 2653), which allowed for the creation of the pilot program to test whether the streamlined procedures, similar to those available for commercial items, can serve as an effective incentive for nontraditional defense contractors to channel investment and innovation into areas that are useful to DoD and provide items developed exclusively at private expense to meet validated military requirements. The DFARS changes proposed by this rule will allow for increased opportunities to utilize the pilot program.

II. Discussion and Analysis

This rule amends DFARS subpart 212.71 by—

- Deleting the term "nontraditional defense contractor" and the associated definition;
- Removing the requirement that pilot program contracts be awarded using competitive procedures;
- Increasing the maximum contract award value threshold for use of the pilot program from $53.5 million to $100 million; and
- Revising the prescription for the provision at 252.212–7002 for use only when the pilot program will be used.

Conforming changes are made to DFARS provision 252.212–7002, Pilot Program for Acquisition of Military-Purpose Nondevelopmental Items, to include removal of the requirement at paragraph (c) for offerors to represent by submission of an offer that the firm is a nontraditional contractor.

This rule also makes one editorial change to provide at DFARS 212.7101 the full text of the definitions of "military-purpose nondevelopmental items" and "nondevelopmental items."

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

DoD does not intend to apply the requirements of section 892 of the NDAA for FY 2016 to contracts at or below the simplified acquisition threshold (SAT) or for the acquisition of commercial items, including commercially available off-the-shelf (COTS) items.

A. Applicability to Contracts at or Below the SAT

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Director, Defense Procurement and Acquisition Policy (DPAP), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations. DoD

did not make that determination. Therefore, this rule does not apply below the simplified acquisition threshold.

B. Applicability to Contracts for the Acquisition of Commercial Items, Including COTS Items

41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial items, and is intended to limit the applicability of laws to contracts for the acquisition of commercial items. 41 U.S.C. 1906 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items. Likewise, 41 U.S.C. 1907 governs the applicability of laws to COTS items, with the Administrator for Federal Procurement Policy the decision authority to determine that it is in the best interest of the Government to apply a provision of law to acquisitions of COTS items in the FAR. The Director, DPAP, is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations. DoD did not make that determination. While FAR part 12 commercial procedures may be used to acquire military purpose nondevelopmental items under this pilot program, the rule will not apply to the acquisition of commercial items.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This rule is necessary to implement section 892 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016.

The objective of the rule is to modify the criteria for the pilot program at DFARS subpart 212.71, Pilot Program for the Acquisition of Military Purpose Nondevelopmental Items, to increase the opportunities for use of the program. The rule removes the criteria that contracts must be awarded to "nontraditional defense contractors" and awards must be made using competitive procedures. The rule also increases the dollar threshold for the program to allow use on procurements up to $100 million.

The changes to the pilot program will have a positive economic impact on small businesses that did not meet the definition of "nontraditional defense contractors" and have developed products that could be applied to a military purpose. According to data available in the Federal Procurement Data System for FY 2015, 6,514 unique small businesses were awarded a DoD contract in excess of the certified cost and pricing threshold ($750,000) and therefore did not meet the definition of "nontraditional defense contractor." Prior to the changes made by this rule these small businesses were not eligible for an award under the pilot program. These small businesses will now be able to participate in the pilot program if they are developing a military purpose nondevelopmental item.

This rule does not impose any new reporting, recordkeeping or other compliance requirements. The rule does not duplicate, overlap, or conflict with any other Federal rules. No significant alternatives were identified during the development of this rule.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2016–D014) in correspondence.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

VII. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. This interim rule implements section 892 of the NDAA for FY 2016 (Pub. L. 114–92), which amended section 866 of the NDAA for FY 2011 (Pub. L. 111–383) to—

- Modify criteria for use of the pilot program in order to increase opportunities for use;
- Remove the requirements under the program to use competitive procedures;
- Remove requirements for awards to be made to nontraditional defense contractors; and
- Increase the threshold for use of the program to contracts up to $100 million.

The purpose of the pilot program is to test whether the streamlined procedures, similar to those available for commercial items, can serve as an effective incentive for nontraditional defense contractors to channel investment and innovation into areas that are useful to DoD and provide items developed exclusively at private expense to meet validated military requirements. This action is necessary because the pilot program expires on December 31, 2019, and, in order to realize any of the benefits from the statutory modifications made by this rule prior to the expiration of the pilot program, the changes made by this rule must take effect immediately. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 212 and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.7100 [Amended]

■ 2. Section 212.7100 is amended by removing "(Pub. L. 111–383)" and adding "(Pub. L. 111–383), as modified by section 892 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92)" in its place.

■ 3. Section 212.7101 is revised to read as follows:

212.7101 Definitions.

As used in this subpart—

Military-purpose nondevelopmental item means a nondevelopmental item that meets a validated military requirement, as determined in writing by the responsible program manager, and has been developed exclusively at private expense. An item shall not be considered to be developed at private expense if development of the item was paid for in whole or in part through—

(1) Independent research and development costs or bid and proposal costs, per the definition in FAR 31.205–18, that have been reimbursed directly or indirectly by a Federal agency or have been submitted to a Federal agency for reimbursement; or

(2) Foreign government funding.

Nondevelopmental item is defined in FAR 2.101 and also includes previously developed items of supply that require modifications other than those customarily available in the commercial marketplace if such modifications are consistent with the requirement at 212.7102–1(c)(1).

212.7102–1 [Amended]

■ 4. Amend section 212.7102–1 by—

■ a. In the introductory text, removing "The contracting officer may enter into contracts with nontraditional defense contractors for" and adding "The contracting officer may utilize this pilot program to enter into contracts for" in its place;

■ b. Removing paragraph (a);

■ c. Redesignating paragraphs (b) through (e) as paragraphs (a) through (d), respectively;

■ d. In the newly redesignated paragraph (b), removing "$53.5 million" and adding "$100 million" in its place; and

■ e. In the newly redesignated paragraph (c)(2), removing "(d)(1)" and adding "(c)(1)" in its place.

212.7103 [Amended]

■ 5. Amend 212.7103 by removing "in all solicitations" and adding "in solicitations" in its place, and removing "for this pilot program" and adding "and plan to use the pilot program" in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.212–7002 [Amended]

■ 6. Amend section 252.212–7002 by—

■ a. Removing the clause date "(JUN 2012)" and adding "(JUN 2016)" in its place;

■ b. In paragraph (a)—

■ i. For the definition of "nondevelopmental item", removing "FAR 2.101 and for the purpose of this subpart also includes" and adding "FAR 2.101 and also includes" in its place, and removing "of DFARS 212.7102–2(d)(1)" and adding "at DFARS 212.7102–1(c)(1)" in its place; and

■ ii. Removing the definition of "nontraditional defense contractor";

■ c. In paragraph (b), removing "Nondevelopmental Items," and adding "Nondevelopmental Items, as modified by section 892 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92)," in its place; and

■ d. Removing paragraph (c).

[FR Doc. 2016–15256 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 216, 225, and 252

[Docket DARS–2015–0045]

RIN 0750–AI69

Defense Federal Acquisition Regulation Supplement: Defense Contractors Performing Private Security Functions (DFARS Case 2015–D021)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to consolidate all requirements for contractors performing private security functions outside the United States applicable to DoD contracts in the DFARS and make changes regarding applicability and high-level quality assurance standards.

DATES: *Effective* June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Julie Hammond, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 81496 on December 30, 2015, to consolidate all requirements for DoD contractors performing private security functions in certain designated operational areas in the DFARS at 225.302 and the clause at 252.225–7039, Defense Contractors Performing Private Security Functions Outside the United States. The rule also proposed to identify the international high-quality assurance standard "ISO 18788: Management System for Private Security Operations" as an approved alternative to the American standard "ANSI/ASIS PSC.1–2012" currently required by DFARS clause 252.225–7039. One respondent submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. There are no changes from the proposed rule in the final rule. A discussion of the comments is provided as follows:

A. Analysis of Public Comments

Comment: The respondent proposed that the clause at DFARS 252.225–7039 be amended to require a contractor to demonstrate compliance with the American National Standard, ANSI/ASIS PSC.1–2012, and/or the International Standard, ISO 18788, by producing a valid certificate of compliance from a nationally accredited certification body.

Response: DoD does not have the statutory authority to require a certificate of compliance from a certification body accredited by a national accreditation body. Section 833 of the National Defense Authorization Act for Fiscal Year 2011 only authorized that the Secretary of Defense "may provide for the consideration of such certifications as a factor in the evaluation of proposals for award of a covered contract for the provision of private security functions." Therefore, no changes are made in the rule.

Comment: The respondent also proposed that the clause explicitly state that the requirements of ANSI/ASIS PSC.1–2012 "are incumbent upon subcontractors on relevant DoD contracts."

Response: The Government does not have privity of contract with subcontractors. However, paragraph (f) of the clause requires contractors to include the substance of the clause, to include paragraph (c)(4) of the clause, in covered subcontracts. Paragraph (c)(4) of the clause requires compliance with ANSI/ASIS PSC.1–2012 or ISO 18788.

B. Other Changes

For consistency in use of terminology in DFARS clause 252.225–7039, in paragraphs (c)(1) and (2), the term "employees of the Contractor" is removed and replaced with "Contractor personnel" in both places.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the Shelf Items

This rule amends the DFARS to consolidate all requirements for contractors performing private security functions outside the United States applicable to DoD contracts in the DFARS and makes changes regarding applicability and high-level quality assurance standards. DFARS clause 252.225–7039, Defense Contractors Performing Private Security Functions Outside the United States, and its prescription at DFARS 225.302–6 are amended. The revisions, however, do not affect applicability of the clause at or below the simplified acquisition threshold or to commercial item acquisitions.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This final rule amends the Defense Federal Acquisition Regulation Supplement (DFARS) to consolidate all requirements for DoD contractors performing private security functions outside the U.S. from the FAR 25.302 and the clause at FAR 52.225–26, Contractors Performing Private Security Functions Outside the Unites States, in DFARS 225.302 and the clause at DFARS 252.225–7039, Defense Contractors Performing Private Security Functions Outside the United States.

The objectives of this rule are as follows:

- Provide DoD contracting officers and contractors a single clause covering all requirements related to the performance of private security functions outside the United States that may be updated by DoD as policies are issued that affect only defense contractors.
- Identify the international high-quality assurance standard "ISO 18788: Management System for Private Security Operations" as an approved alternative to the American standard "ANSI/ASIS PSC.1–2012" currently required by DFARS clause 252.225–7039.

No comments were received from the public in response to the initial regulatory flexibility analysis.

This final rule will apply to defense contractors performing private security functions outside of the United States in designated operational areas under DoD contracts. According to data available in the Federal Procurement Data System for fiscal year (FY) 2013, DoD awarded 159 contracts that required performance outside the United States, although not necessarily in a designated operation area, and cited the National American Industry Classification System code 561612, Security Guards and Patrol Services, of which 33 contracts (21%) were awarded to small businesses. In FY 2014, DoD awarded 123 such contracts, of which 31 contracts (25%) were to small businesses.

The private security contractors are required to report incidents when: (1) A weapon is discharged by personnel performing private security functions; (2) personnel performing private security functions are attacked, killed, or injured; (3) persons are killed or injured or property is destroyed as a result of conduct by Contractor personnel; (4) a weapon is discharged against personnel performing private security functions or personnel performing such functions believe a weapon was so discharged; or (5) active, non-lethal countermeasures (other than the discharge of a weapon) are employed by personnel performing private security functions in response to a perceived immediate threat. As a regular record keeping requirement, private security contractors are required to keep appropriate records of personnel by registering in the Synchronized Predeployment Operational Tracker the equipment and weapons used by its personnel. The complexity of the work to prepare these records requires the expertise equivalent to that of a GS–11, step 5 with clerical and analytical skills to create the documents.

There are no known significant alternatives to the rule. The impact of this rule on small business is not expected to be significant.

VI. Paperwork Reduction Act

This rule contains information collection requirements under the Paperwork Reduction Act (44 U.S.C. chapter 35). The Office of Management and Budget (OMB) has assigned OMB Control Number 0704–0549, entitled "Defense Federal Acquisition Regulation Supplement (DFARS) part 225, Foreign Acquisition, and Defense Contractors Performing Private Security Functions Outside the United States."

List of Subjects in 48 CFR Parts 216, 225, and 252

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 216, 225, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 216, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 216—TYPES OF CONTRACTS

216.405–2–71 [Amended]

■ 2. In section 216.405–2–71, amend paragraph (b) by removing "FAR 52.225–26, Contractors Preforming Private Security Functions" and adding "252.225–7039, Defense Contractors Performing Private Security Functions Outside the United States" in its place.

PART 225—FOREIGN ACQUISITION

225.302–6 [Amended]

■ 3. Amend section 225.302–6 introductory text by removing "Outside the United States," and adding "Outside the United States, instead of FAR clause 52.225–26, Contractors Performing Private Security Functions Outside the United States," in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Amend section 252.225–7039 by—

■ a. Removing the clause date "(JAN 2015)" and adding "(JUN 2016)" in its place;

■ b. Redesignating paragraphs (a) and (b) as paragraphs (c) and (f), respectively;

■ c. Adding new paragraphs (a) and (b);

■ d. Revising newly redesignated paragraph (c);

■ e. Adding paragraphs (d) and (e);

■ f. In newly redesignated paragraph (f), removing "paragraph (b)" and adding "paragraph (f)" in its place.

The additions and revision read as follows:

252.225–7039 Defense Contractors Performing Private Security Functions Outside the United States.

* * * * *

(a) *Definitions.* As used in this clause—

Full cooperation—(1) Means disclosure to the Government of the information sufficient to identify the nature and extent of the incident and the individuals responsible for the conduct. It includes providing timely and complete response to Government auditors' and investigators' requests for documents and access to employees with information;

(2) Does not foreclose any contractor rights arising in law, the FAR or the terms of the contract. It does not require—

(i) The contractor to waive its attorney-client privilege or the protections afforded by the attorney work product doctrine; or

(ii) Any officer, director, owner, or employee of the contractor, including a sole proprietor, to waive his or her attorney-client privilege or Fifth Amendment rights; and

(3) Does not restrict the contractor from—

(i) Conducting an internal investigation; or

(ii) Defending a proceeding or dispute arising under the contract or related to a potential or disclosed violation.

Private security functions means the following activities engaged in by a contractor:

(1) Guarding of personnel, facilities, designated sites or property of a Federal agency, the contractor or subcontractor, or a third party.

(2) Any other activity for which personnel are required to carry weapons in the performance of their duties in accordance with the terms of this contract.

(b) *Applicability.* If this contract is performed both in a designated area and in an area that is not designated, the clause only applies to performance in the designated area. Designated areas are areas outside the United States of—

(1) Contingency operations;

(2) Combat operations, as designated by the Secretary of Defense;

(3) Other significant military operations (as defined in 32 CFR part 159), designated by the Secretary of Defense upon agreement of the Secretary of State;

(4) Peace operations, consistent with Joint Publication 3–07.3; or

(5) Other military operations or military exercises, when designated by the Combatant Commander.

(c) *Requirements.* The Contractor shall—

(1) Ensure that all Contractor personnel who are responsible for performing private security functions under this contract comply with 32 CFR part 159 and any orders, directives, or instructions to contractors performing private security functions that are identified in the contract for—

(i) Registering, processing, accounting for, managing, overseeing and keeping appropriate records of personnel performing private security functions;

(ii) Authorizing, accounting for and registering in Synchronized Predeployment and Operational Tracker (SPOT), weapons to be carried by or available to be used by personnel performing private security functions;

(iii) Identifying and registering in SPOT armored vehicles, helicopters and other military vehicles operated by Contractors performing private security functions; and

(iv) In accordance with orders and instructions established by the applicable Combatant Commander, reporting incidents in which—

(A) A weapon is discharged by personnel performing private security functions;

(B) Personnel performing private security functions are attacked, killed, or injured;

(C) Persons are killed or injured or property is destroyed as a result of conduct by Contractor personnel;

(D) A weapon is discharged against personnel performing private security functions or personnel performing such functions believe a weapon was so discharged; or

(E) Active, non-lethal countermeasures (other than the discharge of a weapon) are employed by personnel performing private security functions in response to a perceived immediate threat;

(2) Ensure that Contractor personnel who are responsible for performing private security functions under this contract are briefed on and understand their obligation to comply with—

(i) Qualification, training, screening (including, if applicable, thorough background checks) and security requirements established by 32 CFR part 159;

(ii) Applicable laws and regulations of the United States and the host country and applicable treaties and international agreements regarding performance of private security functions;

(iii) Orders, directives, and instructions issued by the applicable Combatant Commander or relevant Chief of Mission relating to weapons, equipment, force protection, security, health, safety, or relations and interaction with locals; and

(iv) Rules on the use of force issued by the applicable Combatant Commander or relevant Chief of Mission for personnel performing private security functions;

(3) Provide full cooperation with any Government-authorized investigation of incidents reported pursuant to paragraph (c)(1)(iv) of this clause and incidents of alleged misconduct by personnel performing private security functions under this contract by providing—

(i) Access to employees performing private security functions; and

(ii) Relevant information in the possession of the Contractor regarding the incident concerned; and

(4) Comply with ANSI/ASIS PSC.1–2012, American National Standard, Management System for Quality of Private Security Company Operations—Requirements with Guidance or the International Standard ISO 18788, Management System for Private Security Operations—Requirements with Guidance (located at *http://www.acq.osd.mil/log/PS/psc.html*).

(d) *Remedies.* In addition to other remedies available to the Government—

(1) The Contracting Officer may direct the Contractor, at its own expense, to remove and replace any Contractor or subcontractor personnel performing private security functions who fail to comply with or violate applicable requirements of this clause or 32 CFR part 159. Such action may be taken at the Government's discretion without prejudice to its rights under any other provision of this contract;

(2) The Contractor's failure to comply with the requirements of this clause will be included in appropriate databases of past performance and considered in any responsibility determination or evaluation of past performance; and

(3) If this is an award-fee contract, the Contractor's failure to comply with the requirements of this clause shall be considered in the evaluation of the Contractor's performance during the relevant evaluation period, and the Contracting Officer may treat such failure to comply as a basis for reducing

or denying award fees for such period or for recovering all or part of award fees previously paid for such period.

(e) *Rule of construction.* The duty of the Contractor to comply with the requirements of this clause shall not be reduced or diminished by the failure of a higher- or lower-tier Contractor or subcontractor to comply with the clause requirements or by a failure of the contracting activity to provide required oversight.

* * * * *

[FR Doc. 2016–15247 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 225

[Docket DARS–2016–0007]

RIN 0750–AI88

Defense Federal Acquisition Regulation Supplement: Treatment of Interagency and State and Local Purchases (DFARS Case 2016–D009)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that is entitled "Treatment of Interagency and State and Local Purchases." This section provides that contracts executed by DoD as a result of the transfer of contracts from the General Services Administration or for which DoD serves as an item manager for products on behalf of the General Services Administration shall not be subject to certain domestic source restrictions, to the extent that such contracts are for the purchase of products by other Federal agencies or State or local governments.

DATES: Effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 81 FR 17053 on March 25, 2016, to implement section 897 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92). Section 897 provides that contracts executed by DoD as a result of the transfer of contracts from the General Services Administration or for which DoD serves as an item manager for products on behalf of the General Services Administration shall not be subject to the requirements under 10 U.S.C. chapter 148 (National Defense Technology and Industrial Base, Defense Investment, and Defense Conversion), to the extent that such contracts are for the purchase of products by other Federal agencies or State or local governments. One respondent submitted public comments in response to the proposed rule.

II. Discussion and Analysis

There are no changes from the proposed rule made in the final rule. The one respondent that submitted a comment fully supported the proposed rule.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule implements section 897 of the National Defense Authorization Act for Fiscal Year 2016. The objective of this rule is to eliminate the domestic source restrictions of 10 U.S.C. chapter 148 when contracts executed by DoD as a result of the transfer of contracts from the General Services Administration or for which DoD serves as an item manager for products on behalf of the General Services Administration, to the extent that such contracts are for the purchase of products by other Federal agencies or State or local governments.

There were no significant issues raised by the public in response to the initial regulatory flexibility analysis.

DoD does not anticipate frequent application of this rule. The rule removes the domestic source restriction for the specified items in the specified circumstances. In the rare instance in which the circumstances of the statute apply, it is possible that an item could be acquired from a foreign source, rather than a domestic source, which could potentially be a small business. It is not possible to estimate the number of small entities that may be affected, because it is unknown the extent to which the given circumstances may occur.

There are no projected reporting, recordkeeping, or other compliance requirements.

DoD has not identified any alternatives that would minimize any economic impact on small entities and still meet the requirements of the statute.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 225

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 225 is amended as follows:

PART 225—FOREIGN ACQUISITION

■ 1. The authority citation for 48 CFR part 225 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 225.7002–2 by adding paragraph (o) to read as follows:

225.7002–2 Exceptions.

* * * * *

(o) Acquisitions that are interagency, State, or local purchases that are executed by DoD as a result of the transfer of contracts from the General Services Administration or for which DoD serves as an item manager for products on behalf of the General Services Administration. According to section 897 of the National Defense

Authorization Act for Fiscal Year 2016 (Pub. L. 114–92), such contracts shall not be subject to requirements under chapter 148 of title 10, United States Code (including 10 U.S.C. 2533a), to the extent such contracts are for purchases of products by other Federal agencies or State or local governments.

[FR Doc. 2016–15249 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2016–0022]

RIN 0750–AI98

Defense Federal Acquisition Regulation Supplement: New Designated Country—Ukraine (DFARS Case 2016–D026)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to add Ukraine as a new designated country under the World Trade Organization Government Procurement Agreement.

DATES: Effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

On November 11, 2015, the World Trade Organization (WTO) Committee on Government Procurement approved the accession of Ukraine to the WTO Government Procurement Agreement (GPA). Ukraine submitted its instrument of accession to the Secretary General of the WTO on April 18, 2016. The GPA entered into force for Ukraine on May 18, 2016. The United States, which is also a party to the GPA, has agreed to waive discriminatory purchasing requirements for eligible products and suppliers of Ukraine beginning on May 18, 2016. Therefore, this rule adds Ukraine to the list of WTO GPA countries wherever it appears in the DFARS, as part of the definition of "designated country".

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule only updates the list of designated countries in the DFARS by adding the newly designated country of Ukraine. The definition of "designated country" is updated in each of the following clauses; however, this revision does not impact the clause prescriptions for use, or applicability at or below the simplified acquisition threshold, or applicability to commercial items. The clauses are: DFARS 252.225–7017, Photovoltaic Devices; DFARS 252.225–7021, Trade Agreements; and DFARS 252.225–7045, Balance of Payments Program—Construction Material Under Trade Agreements.

III. Publication of This Final Rule for Public Comment is not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707 entitled "Publication of Proposed Regulations." Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it is just updating the lists of designated countries in order to reflect that Ukraine is now a member of the WTO GPA. These requirements affect only the internal operating procedures of the Government.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

VI. Paperwork Reduction Act

This rule affects the information collection requirements in the provisions at DFARS 252.225–7020, Trade Agreements Certificate, and 252.225–7018, Photovoltaic Devices—Certificate, currently approved under OMB Control Number 0704–0229, entitled "Defense Federal Acquisition Regulation Supplement Part 225, Foreign Acquisition, and related clauses," in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible, because the rule only affects the response of an offeror that is offering a product of Ukraine in an acquisition that exceeds $191,000. In 252.225–7018, the offeror of a product from Ukraine must now check a box at (d)(6)(i) of the provision. However, the offeror no longer needs to list a product from Ukraine under "other end products" at 252.225–7020(c)(2), because Ukraine is now a designated country.

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

252.225–7017 [Amended]

■ 2. Amend section 252.225–7017 by—

■ a. Removing the clause date of "(JAN 2016)" and adding "(JUN 2016)" in its place; and

■ b. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine".

252.225–7021 [Amended]

■ 3. Amend section 252.225–7021 by—

■ a. Removing the basic clause date of "(OCT 2015)" and adding "(JUN 2016)" in its place;
■ b. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine"; and
■ c. In the Alternate II clause—
■ i. Removing the clause date of "(OCT 2015)" and adding "(JUN 2016)" in its place; and
■ ii. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine".

252.225–7045 [Amended]

■ 4. Amend section 252.225–7045 by—
■ a. Removing the basic clause date of "(OCT 2015)" and adding "(JUN 2016)" in its place;
■ b. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine";
■ c. In the Alternate I clause—
■ i. Removing the clause date of "(OCT 2015)" and adding "(JUN 2016)" in its place; and
■ ii. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine";
■ d. In the Alternate II clause—
■ i. Removing the clause date of "(OCT 2015)" and adding "(JUN 2016)" in its place; and
■ ii. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine"; and
■ e. In the Alternate III clause—
■ i. Removing the clause date of "(OCT 2015)" and adding "(JUN 2016)" in its place; and
■ ii. In paragraph (a), in the definition of "designated country" in paragraph (i), adding, in alphabetical order, the country of "Ukraine".

[FR Doc. 2016–15258 Filed 6–29–16; 8:45 am]
BILLING CODE 5001–06–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 190

[Docket No. PHMSA–2016–0010]

RIN–2137–AF16

Pipeline Safety: Inflation Adjustment of Maximum Civil Penalties

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Interim final rule.

SUMMARY: PHMSA is revising references in its regulations to the maximum civil penalties for violations of the Federal Pipeline Safety Laws, or any PHMSA regulation or order issued thereunder. Under the "Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015," which further amended the "Federal Civil Penalties Inflation Adjustment Act of 1990," federal agencies are required to adjust their civil monetary penalties effective August 1, 2016, and then annually thereafter, to account for changes in inflation.

PHMSA finds good cause to amend the regulation related to civil penalties without notice and opportunity for public comment. For the reasons described below, advance public notice is unnecessary.

DATES: The effective date of this interim final rule is August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Aaron Glaser, Attorney-Advisor, Pipeline Safety Division, Office of Chief Counsel, Pipeline and Hazardous Materials Safety Administration, by telephone at 202–366–6318 or by email at *aaron.glaser@dot.gov;* Melanie Stevens, Attorney-Advisor, Pipeline Safety Division, Office of Chief Counsel, Pipeline and Hazardous Materials Safety Administration, by telephone at 202–366–5466 or by email at *melanie.stevens@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Procedures

Background

Section 701 of the "Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015" (Pub. L. 114–72) (the 2015 Act) amended the "Federal Civil Penalties Inflation Adjustment Act of 1990" (Pub. L. 101–410) (Inflation Adjustment Act) to require that federal agencies adjust their civil penalties with an initial "catch-up" adjustment through an interim final rulemaking by July 1, 2016, as well as make subsequent annual adjustments for inflation. This interim rule adjusts the maximum civil penalties assessed under 49 U.S.C. 60101, *et seq.*, or regulations or orders issued thereunder. These adjusted penalties will apply to violations occurring on or after the effective date of August 1, 2016.

On February 24, 2016, the Office of Management and Budget (OMB) issued a "Memorandum for the Heads of Executive Departments and Agencies, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015," M–16–06 (OMB Memorandum M–16–06), providing guidance to federal agencies on how to update their civil penalties pursuant to the 2015 Act. OMB Memorandum M–16–06 directs agencies to use multipliers to adjust their civil monetary penalties, or the minimum and maximum penalties, based on the year the penalty was established or last adjusted by statute or regulation other than under the Inflation Adjustment Act (Base Year). For the catch-up adjustment, the agency must use the multiplier, based on the Consumer Price Index for October 2015, provided in the table of OMB Memorandum M–16–06 and multiply it by the current maximum penalty amount. After making an adjustment, all penalty levels must be rounded to the nearest dollar, but no penalty level may be increased by more than 150 percent of corresponding penalty levels in effect on November 2, 2015.

PHMSA is revising the maximum civil penalty amounts in its regulations, consistent with the process outlined in OMB Memorandum M–16–06. The "Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011" (the 2011 Act) (Public Law No: 112–90) adjusted the maximum civil penalties for violations under 49 U.S.C. 60101, *et seq.* In 2013, PHMSA amended 49 Code of Federal Regulations (CFR) § 190.223(a) to conform to the 2011 Act, effective January 2, 2012. (78 FR 58897). Based on the 2012 effective date, a multiplier 1.02819 was used to calculate the updated penalties for violations under 49 U.S.C. 60101, *et seq.*, and any regulation or order issued thereunder. The civil penalty amounts for violations of 49 U.S.C. 60103 and 60111 were last set by Congress in 1994 with the Revision of Title 49, United States Code Annotated, Transportation (Pub. L. 103–272), and last adjusted by PHMSA in 1996 via regulation amending 49 CFR 190.223(c) (61 FR 18515). The 1996 multiplier of 1.50245 was used to calculate the updated penalties for violations of 49 U.S.C. 60103 and 60111. Lastly, the penalty amount for violations of 49 U.S.C. 60129 was last set by Congress in 2002 with the passage of the "Pipeline Safety Improvement Act of 2002," (Pub. L. 107–355), and last adjusted by PHMSA in 2005 via regulation amending 49 CFR 190.223(d) (70 FR 11137). The 2005 multiplier of 1.19397 was used to calculate the updated penalties for violations of 49 U.S.C. 60129. These revised penalties are shown as follows:

Violated statute	CFR Citation	Base year	Current maximum civil penalty	Revised maximum civil penalty
49 U.S.C. 60101 *et seq.*, and any regulation or order issued thereunder..	49 CFR 190.223(a)	2012	$200,000 for each violation for each day the violation continues, with a maximum penalty not to exceed $2,000,000 for a related series of violations.	$205,638 for each violation for each day the violation continues, with a maximum penalty not to exceed $2,056,380 for a related series of violations.
49 U.S.C. 60103;49 U.S.C. 60111.	49 CFR 190.223(a)	1996	A penalty not to exceed $50,000, which may be in addition to other penalties under 40 U.S.C. 60101, *et seq.*	An administrative civil penalty not to exceed $75,123, which may be in addition to other penalties assessed under 49 U.S.C. 60101, *et seq.*
49 U.S.C. 60129	49 CFR 190.223(d)	2005	A penalty not to exceed $1,000	A penalty not to exceed $1,194.

The 2015 Act only applies to penalties prospectively and does not retrospectively change any civil penalties previously assessed or enforced.

Starting in January 2017, PHMSA is required to publish in the **Federal Register** annual inflation adjustments for each penalty levied under 49 U.S.C. 60101, *et seq.*, and do so no later than January 15 of each year.

The 2015 Act does not alter PHMSA's existing authority to assess penalties levied for violations under 49 U.S.C. 60101, *et seq.* Additionally, if future penalties or penalty adjustments are enacted by statute or regulation, PHMSA will not adjust these penalties for inflation in the first year after these penalties are in effect. PHMSA will apply new annual penalty levels to any penalties assessed on or after the date these new levels take effect.

II. Justification for Interim Final Rule

The Administrative Procedure Act (APA) authorizes agencies to forego providing the opportunity for prior public notice and comment if an agency finds good cause that notice and public procedure are unnecessary. *See* 5 U.S.C. 553(b)(3)(B). In this instance, PHMSA is required under the 2015 Act and directed by the OMB Guidance to publish this rule by July 1, 2016, with the penalty levels stated herein to take effect no later than August 1, 2016. Further, PHMSA is mandated by the 2015 Act and directed by the OMB Guidance to adjust the penalty levels pursuant to the specific procedures also stated herein. Any public comments received through notice and public procedure would therefore not affect PHMSA's obligation to comply with the 2015 Act or OMB Guidance, nor would they affect the methods used by PHMSA to adjust the penalty levels. PHMSA, therefore, finds good cause that APA notice and comment are unnecessary for this interim final rule.

III. Rulemaking Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This rule is published under the authority of the 2015 Act, as well 49 U.S.C. 60101 *et seq.* These statutes provide PHMSA with the authority to levy civil penalties for violations of the federal Pipeline Safety Laws. The 2015 Act requires penalties levied by federal agencies pursuant to these laws to be adjusted, and for the new adjusted penalties to take effect no later than August 1, 2016. Further, beginning in January 2017, the 2015 Act requires such penalties to be adjusted on an annual basis no later than January 15 of each year.

B. Executive Orders 12866 and 13563, and DOT Regulatory Policies and Procedures

This rule has been evaluated in accordance with existing DOT policies and procedures and determined to be non-significant under Executive Orders 12866 and 12563. This rule is considered a regulatory action under Section 3(e) of Executive Order 12866, and pursuant to Section 6(a)(3)(D) of Executive Order 12866. Further, this interim final rule is not significant under the Regulatory Policies and Procedures of the Department of Transportation because it is limited to a ministerial act on which the agency has no discretion and the economic impact of this rule is minimal. (44 FR 11034). Accordingly, preparation of a regulatory evaluation is not warranted.

This rule imposes no new costs upon persons conducting operations in compliance with federal pipeline statutes and regulations. Those operators not in compliance with these statutes and regulations may experience an increased cost, based on the penalties levied against them for non-compliance; however, this is an avoidable, variable cost and thus, is not considered in any evaluation of the significance of this regulatory action. The amendments in this rule could provide a deterrent effect that could potentially lead to safety benefits; however, PHMSA does not expect such benefits to be significant. Overall, it is anticipated that costs and benefits from this rule would be minimal in real dollars.

C. Executive Order 13132

PHMSA has analyzed this rule according to Executive Order 13132 on federalism. The interim final rule does not have a substantial direct effect on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. The rule neither imposes substantial direct compliance costs on state and local governments nor preempts state law governing intrastate pipelines. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 on consultation and coordination with Indian tribal governments. Because the rule does not have tribal implications, does not impose substantial direct compliance costs, and is required by statute, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Executive Order 13211

This rule is not a "significant energy action" under Executive Order 13211 on actions concerning regulations that significantly affect energy supply, distribution, or use. It is not likely to have a significant adverse effect on supply, distribution, or energy use. Further, the Office of Information and Regulatory Affairs (OIRA) within OMB has not designated this rule as a significant energy action.

F. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

The Regulatory Flexibility Act (5 U.S.C. 601–611) requires each agency to analyze proposed regulations and assess their impact on small businesses and other small entities to determine whether the rule is expected to have a significant impact on a substantial number of small entities. The provisions of this interim final rule may apply specifically to all businesses using pipelines to transport hazardous liquids, gas, and LNG in interstate commerce. Therefore, PHMSA certifies this rule would not have a significant economic impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

This rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $155,000,000 or more, adjusted for inflation, in any year for either state, local, or tribal governments, in the aggregate, or to the private sector, and is the least-burdensome alternative that achieves the objective of the rule.

H. Paperwork Reduction Act

This interim final rule imposes no new requirements for recordkeeping or reporting.

I. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4375), requires federal agencies to consider the consequences of major federal actions and prepare a detailed statement on actions significantly affecting the quality of the human environment. When developing potential regulatory requirements, PHMSA evaluates those requirements to consider the environmental impact of these amendments. Specifically, PHMSA evaluates the risk of release and resulting environmental impact; risk to human safety, including any risk to first responders; if the proposed regulation would be carried out in a defined geographic area; and the resources, especially in environmentally sensitive areas, that could be impacted by any proposed regulations.

This interim final rule would be generally applicable to pipeline operators, and would not be carried out in a defined geographic area. The adjusted, increased civil penalties listed in this interim final rule may act as a deterrent to those violating the Federal Pipeline Safety Laws, or any PHMSA regulation or order issued thereunder. This may result in a positive environmental impact as a result of increased compliance with the Federal Pipeline Safety Laws and any PHMSA regulations or orders issued thereunder. Based on the above discussion, PHMSA concludes there are no significant environmental impacts associated with this interim final rule.

J. Privacy Act

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, pages 19477–78) or online at *https://www.federalregister.gov/articles/2000/04/11/00-8505/privacy-act-of-1974-systems-of-records* or *https://www.gpo.gov/fdsys/pkg/FR-2000-04-11/pdf/00-8505.pdf.*

K. Executive Order 13609 and International Trade Analysis

Sections 3 and 4 of Executive Order 13609 direct an agency to conduct a regulatory analysis and ensure that a proposed rule does not cause unnecessary obstacles to foreign trade. This requirement applies if a rule constitutes a significant regulatory action, or if a regulatory evaluation must be prepared for the rule. This interim final rule is not a significant regulatory action, but a regulatory action under Section 3(e) of Executive Order 12866. PHMSA is not required under Executive Orders 12866 and 13563 to submit a regulatory analysis.

L. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in the spring and fall of each year. The RIN contained in the heading of this document can be used to cross-reference this action in the Unified Agenda.

List of Subjects in 49 CFR Part 190

Administrative practice and procedure, Penalties, Pipeline safety.

In consideration of the foregoing, PHMSA is amending 49 CFR part 190 as follows:

PART 190—PIPELINE SAFETY ENFORCEMENT AND REGULATORY PROCEDURES

■ 1. The authority citation for part 190 is revised to read as follows:

Authority: 33 U.S.C. 1321(b); 49 U.S.C. 60101 *et seq.;* 49 CFR 1.97; Pub. L. 114–74, section 701; Pub. L. No: 112–90, section 2; Pub. L. 101–410, sections 4–6.

■ 2. Section 190.223 is amended by revising paragraphs (a) though (d) to read as follows:

§ 190.223 Maximum penalties.

(a) Any person found to have violated a provision of 49 U.S.C. 60101 *et seq.,* or any regulation or order issued thereunder is subject to an administrative civil penalty not to exceed $205,638 for each violation for each day the violation continues, except that the maximum administrative civil penalty may not exceed $2,056,380 for any related series of violations.

(b) Any person found to have violated a provision of 33 U.S.C. 1321(j) or any regulation or order issued thereunder is subject to an administrative civil penalty under 33 U.S.C. 1321(b)(6), as adjusted by 40 CFR 19.4.

(c) Any person found to have violated any standard or order under 49 U.S.C. 60103 is subject to an administrative civil penalty not to exceed $75,123, which may be in addition to other penalties to which such person may be subject under paragraph (a) of this section.

(d) Any person who is determined to have violated any standard or order under 49 U.S.C. 60129 is subject to an administrative civil penalty not to exceed $1,194, which may be in addition to other penalties to which such person may be subject under paragraph (a) of this section.

* * * * *

Issued in Washington, DC, under authority delegated in 49 CFR Part 1.97.

Marie Therese Dominguez,

Administrator.

[FR Doc. 2016–15529 Filed 6–29–16; 8:45 am]

BILLING CODE 4910–60–P

SURFACE TRANSPORTATION BOARD

49 CFR Chapter X

[Docket No. EP 719]

Small Entity Size Standards Under the Regulatory Flexibility Act

AGENCY: Surface Transportation Board (Board or STB).

ACTION: Final statement of agency policy.

SUMMARY: On July 11, 2013, the Board issued a notice of proposed size standards for purposes of the Regulatory Flexibility Act, along with a request for public comment. This decision discusses the comment received in response to the proposed size standards

and adopts the proposed standard as the final statement of agency policy concerning the definition of "small business."

DATES: This policy statement is effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Amy Ziehm at (202) 245–0391. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their regulations on small entities,[1] analyze effective alternatives that minimize the impact to small entities, and make their analyses available for public comment. The Small Business Administration (SBA) developed "size standards" to clarify the term small business and to carry out the purposes of the Small Business Act. Agencies can then use the SBA's size standards for purposes of defining "small entities" to comply with the RFA. However, an agency may establish other definitions for small business that are appropriate to the agency's activities after consultation with the SBA's Office of Advocacy and after opportunity for public comment. 5 U.S.C. 601(3). The SBA has promulgated regulations that classify "Line-Haul Railroads" with 1,500 or fewer employees and "Short Line Railroads" with 500 or fewer employees as small businesses. 13 CFR 121.201 (industry subsector 482).

On July 16, 2013, the Board served a notice proposing its own small entity size standards for purposes of the RFA, along with a request for comment. 78 FR 42,484 (July 16, 2013). After consulting with the SBA's Office of Advocacy, the Board proposed to establish a small entity size standard based on its longstanding classification system, which classifies freight railroads as Class I, Class II, or Class III based on annual operating revenues.[2] Specifically, the Board proposed to define "small business" as only those rail carriers that would be classified as Class III carriers. The Board stated that it believed that this definition is more realistic and useful than the general definitions previously established by the SBA. The Board also noted that this would create consistency with the Federal Railroad Administration (FRA), which in 2003 adopted the Class III standard as its definition of a small business.

The American Short Line and Regional Railroad Association (ASLRRA) submitted a comment on August 5, 2013, opposing the Board's proposal. ASLRRA agrees with the SBA's current definition of small business, which uses the number of employees, rather than revenue, as the relevant metric. It maintains that revenue is an unreliable metric for determining whether a railroad is a small business because railroads are "so capital intensive their revenues must provide a return on that huge investment or they cannot stay in business" and because "small railroad revenues are driven largely by the types of commodities they happen to carry." (ASLRRA Comment 3) ASLRRA argues that changing the definition would exclude many Class II railroads from the small business designation, and would thus "strip them from the financial impact review that is the right of small entities during the rulemaking process pursuant to the Regulatory Flexibility Act." (*Id.*) Finally, ASLRRA claims that Class II railroads have little in common with Class I railroads and share more characteristics with the smaller Class III railroads. (*Id.* at 4.)

Despite ASLRRA's objection to the use of our revenue classifications over employee counts to define a small business, we find that it is the more appropriate basis for doing so. Even if, as ASLRRA argues, there is some variation between carriers of similar employment levels due, in part, to the types of commodities being shipped, that alone does not mean that employment level represents the better approach to defining a small business. As the Board explained in the notice, the system of classifying railroads based on revenue is used pervasively by the Board and the railroad industry. The agency has used revenue to classify rail carriers since as early as 1911, and the agency's governing statute, precedent, and regulations often impose different requirements depending on the class of carrier involved. The validity of using revenues to define carrier size has thus been sufficiently demonstrated over time. ASLRRA has not demonstrated that using a size standard based on employment levels is superior to the revenue basis the agency and railroad industry have used for decades.

We now address whether the definition of small business should or should not include Class II carriers. The Board acknowledges ASLRRA's concerns regarding Class II rail carriers and recognizes the differences between Class I, Class II, and Class III railroads. However, the Board does not believe that Class II carriers should be classified as small businesses. Under the Board's governing statutes and regulations, special exceptions are made for Class III carriers, but not Class II carriers.[3] The Board's decision to limit the definition of small business solely to Class III carriers is therefore consistent with the broader regulatory scheme and merely formalizes what is already a common understanding of a small business in the railroad industry.

In addition, the Board also believes there is significant utility in maintaining consistency with the practices of the Federal Railroad Administration, which adopted the same definition of small entity for RFA purposes. *Final Policy Statement Concerning Small Entities Subject to the Railroad Safety Laws*, 68 FR 24,891 (May 9, 2003); *see also Interim Policy Statement Concerning Small Entities Subject to the Railroad Safety Laws*, 62 FR 43,024 (Aug. 11, 1997). Having two agencies that play complementary roles in railroad industry regulation use different definitions of small business could result in lack of uniformity in the adoption of Federal regulations. In particular, an entity could be considered a small entity for purposes of FRA rules but not a small entity for purposes of STB rules. Not altering the Board's definition of a small business would also perpetuate the incongruous situation of the FRA relying on the Board's classification system as a basis for defining a small business, but the Board not doing so itself.

For the reasons set forth above, the Board will define small business for the purpose of Regulatory Flexibility Act analyses to mean those rail carriers classified as Class III rail carriers under 49 CFR 1201.1–1.

It is ordered:

1. For the purpose of Regulatory Flexibility Act analyses, the Board adopts the definition of "small business" to mean those rail carriers

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[1] The RFA defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." 5 U.S.C. 601(6).

[2] Class III carriers have annual operating revenues of $20 million or less in 1991 dollars, or $38,060,383 or less when adjusted for inflation using 2014 data. Class II rail carriers have annual operating revenues of up to $250 million in 1991 dollars or up to $475,754,802 when adjusted for inflation using 2014 data. The Board calculates the revenue deflator factor annually and publishes the railroad revenue thresholds on its Web site. 49 CFR 1201.1–1.

[3] For example, the Board created a class exemption for acquisitions of rail lines by Class III carriers (49 CFR *Subpart E—Exempt Transactions Under 49 U.S.C. 10902 for Class III Rail Carriers);* Class III carriers are exempt from labor protective conditions for line acquisitions and mergers (49 U.S.C. 11326(c)); and Class III carriers are the only carriers allowed to file Feeder Line applications (49 U.S.C. 10907(a)).

classified as Class III rail carriers under 49 CFR 1201.1–1.

2. A copy of this decision will be served upon the Chief Counsel for Advocacy, Office of Advocacy, U.S. Small Business Administration.

3. Notice of this decision will be published in the **Federal Register**.

4. This decision is effective on June 30, 2016.

Decided: June 22, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman. Commissioner Begeman dissented with a separate expression.

Tia Delano,

Clearance Clerk.

COMMISSIONER BEGEMAN, dissenting:

I am a strong proponent of the notice and comment process and find it especially important given the Board's extreme ex parte communication restrictions. So when the only comments received are from the stakeholders most affected, and those stakeholders express strong opposition to a Board proposal, I think we are obligated to carefully consider the concerns expressed and reassess the wisdom of our approach. Upon doing so here, I have concluded this proposal should be withdrawn.

The American Short Line and Regional Railroad Association (ASLRRA), which represents 550 Class II and Class III rail carriers across the country, filed in strong opposition to the Board's July 2013 proposal to alter its small entity definition for Regulatory Flexibility Act (RFA) purposes. ASLRRA argued that the Board's proposal to use revenue rather than number of employees (the measure developed by the Small Business Administration that agencies can use to comply with the RFA) would effectively lump all Class II carriers with Class I carriers for RFA purposes, an unreasonable outcome given the significant differences between those carrier types. ASLRRA further argued that the Board's proposal would be "detrimental to Class II carriers." I find ASLRRA's concerns alarming.

I am not convinced that the action the Board is taking today is necessary or somehow worth the potential harms described by ASLRRA. After all, the majority's decision does not dispute ASLRRA's claims. It appears the driving factor in this decision is the majority's desire to create "consistency" with the Federal Railroad Administration. While consistency may be fine, it certainly is not a very compelling reason since the two agencies have used different small business definitions for 13 years without issue.

There are a host of stale proceedings piled up at the Board and I am all for the Chairman moving the docket. But if (after three years) the majority was merely going to dismiss the only comment received from representatives of the parties affected, there was no real point in the Board inviting comment in the first place. I dissent.

[FR Doc. 2016–15437 Filed 6–29–16; 8:45 am]

BILLING CODE 4915–01–P

Proposed Rules

Federal Register
Vol. 81, No. 126
Thursday, June 30, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 305

[Docket No. APHIS–2013–0081]

RIN 0579–AD90

Standardizing Phytosanitary Treatment Regulations: Approval of Cold Treatment and Irradiation Facilities; Cold Treatment Schedules; Establishment of Fumigation and Cold Treatment Compliance Agreements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the phytosanitary treatment regulations to establish generic criteria that would allow for the approval of new cold treatment facilities in the Southern and Western States of the United States. These criteria, if met, would allow us to approve new cold treatment facilities without rulemaking and facilitate the importation of fruit requiring cold treatment while continuing to provide protection against the introduction of pests of concern into the United States. We are also proposing to amend the fruit cutting and inspection requirements in the cold treatment regulations in order to expand cutting and inspection to commodities that have been treated for a wider variety of pests of concern. This action would provide for a greater degree of phytosanitary protection. We are also proposing to add requirements concerning the establishment of compliance agreements for all entities that operate fumigation facilities. Finally, we are proposing to harmonize language concerning State compliance with facility establishment and parameters for the movement of consignments from the port of entry or points of origin in the United States to the treatment facility in the irradiation treatment regulations with proposed language in the cold treatment regulations. These actions would serve to codify and make enforceable existing procedures concerning compliance agreements for these facilities.

DATES: We will consider all comments that we receive on or before August 29, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0081.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0081, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0081* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Lamb, Senior Regulatory Policy Specialist, IRM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2103.

SUPPLEMENTARY INFORMATION:

Background

The phytosanitary treatments regulations in 7 CFR part 305 set out general requirements for certifying or approving treatment facilities and for performing treatments listed in the Plant Protection and Quarantine (PPQ) Treatment Manual[1] for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. Within part 305, § 305.6 (referred to below as the regulations) sets out requirements for treatment procedures, monitoring, facilities, and enclosures needed for performing sustained refrigeration (cold treatment) sufficient to kill certain insect pests associated with imported fruits and vegetables and with regulated articles moved interstate from quarantined areas within the United States. Under the regulations, all domestic facilities used to provide cold treatment for these articles must operate under a compliance agreement with the Animal and Plant Health Inspection Service (APHIS) and be certified as capable of delivering required cold treatment and handling articles to prevent reinfestation of treated articles. An inspector[2] monitors all domestic treatments. The regulations require safeguards to prevent the escape of pests during transportation to and while at the facility. These include, but are not limited to, inspections, precooling, and physical separation of untreated and treated articles. The facility must maintain records of all treatments and must periodically be recertified. These conditions have allowed for the safe, effective treatment of many different kinds of articles, as is demonstrated by the track record of cold treatment facilities currently operating in the United States and other countries.

Cold Treatment in Southern and Western States

In § 305.6, paragraph (b) allows cold treatment facilities to be located in the area north of 39° latitude and east of 104° longitude. When the cold treatment regulations were established, areas outside of these coordinates were identified as having conditions favorable for the establishment of exotic fruit flies. The location restrictions served as an additional safeguard against the possibility that fruit flies could escape from imported articles prior to treatment and become established in the United States.

Although the regulations initially did not allow cold treatment facilities to be located in Southern and Western States, APHIS periodically received requests for exemptions. In response to these requests, APHIS conducted site-specific evaluations for these locations and determined that regulated articles can be safely transported to, handled in, and treated by specific cold treatment facilities outside of the areas established by the regulations under special conditions to mitigate the possible escape of pests of concern. Over the years, APHIS has amended its regulations to allow cold treatment facilities to be located at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; Hartsfield-Atlanta International Airport, Atlanta, GA; and, most recently, MidAmerica St. Louis Airport, Mascoutah, IL.

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[1] The PPQ Treatment Manual is available at (*http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf*).

[2] Section 305.1 defines an *inspector* as "Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part."

In addition to those requests, certain importers of fruits and vegetables have shown considerable interest in locating cold treatment facilities in places that are not currently allowed under the regulations (*e.g.*, Miami and Port Everglades, FL, and Savannah, GA).

Proposed Changes to the Regulations Governing Cold Treatment Facilities in Southern and Western States

In anticipation of future requests to locate additional cold treatment facilities in the Southern and Western States of the United States, we are proposing to establish generic phytosanitary criteria that would replace the current location-specific criteria for cold treatment facilities at the ports mentioned previously and would also apply to new cold treatment facilities in the Southern and Western States of the United States. The proposed criteria are similar to those successfully used for the approval of new irradiation facilities in the Southern United States found in § 305.9 of the regulations, as untreated fruit moving to irradiation facilities in those States presents the same pest risks as untreated fruit moving to cold treatment facilities. We would not require currently approved cold treatment facilities in Southern and Western States to immediately meet the proposed generic criteria since the specific requirements presently in place for each facility would continue to provide adequate phytosanitary protection. Nevertheless, we would require currently approved facilities to meet the new generic requirements as each comes up to renew its required recertification, which takes place at 3 year intervals or at other times as determined by APHIS based on treatments performed, commodities handled, and operations conducted at the facility.

All cold treatment facilities in the Southern and Western States would be required to meet the current criteria for cold treatment facilities north of 39° latitude and east of 104° longitude, in addition to the proposed generic criteria. These generic criteria would be supplemented as necessary by additional measures, which would be described in a compliance agreement (discussed below), based on pests of concern associated with specific regulated articles to be treated at the facility and the location of the specific facility. Facilities that meet these requirements could then be approved for the treatment of regulated articles that are imported, moved interstate from Hawaii or U.S. territories, or moved interstate from areas quarantined for certain pests of concern.

Using APHIS-approved cold treatment facilities located in the United States, rather than those located outside of the United States, to treat imported articles offers the advantage of greater ease of monitoring treatment. Using generic criteria, rather than site by site approval, for future cold treatment facilities located in Southern and Western States would make explicit our criteria for approving these facilities while eliminating the need to undertake rulemaking in order to approve new facilities.

To support this action, we have prepared a treatment evaluation document (TED) entitled "Phytosanitary Criteria for Establishing Locations for Cold Treatment Facilities in Areas of the United States Currently Not Allowed." Copies of the TED may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT** and may be viewed on the Internet on the *Regulations.gov* Web site or in our reading room (see **ADDRESSES** above for instructions for accessing *Regulations.gov* and the location and hours of the reading room). In the TED, we concluded that the pest risks presented by cold treatment facilities in the Southern and Western States can be adequately managed through the use of special conditions to mitigate the possible escape of pests of concern.

We are therefore proposing to amend the regulations by replacing the current specific criteria for cold treatment facilities at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; MidAmerica St. Louis Airport, Mascoutah, IL; and Hartsfield-Atlanta International Airport, Atlanta, GA, in § 305.6 with generic phytosanitary criteria for any cold treatment facility in a Southern or Western State. The proposed generic criteria would have to be followed in addition to the current requirements that apply to all cold treatment facilities. The proposed generic criteria for new facilities in the Southern and Western States are based on the current conditions for allowing cold treatment facilities at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; MidAmerica St. Louis Airport, Mascoutah, IL; and Hartsfield-Atlanta International Airport, Atlanta, GA.

In proposed paragraph (b)(1)(i) of § 305.6, we would require that prospective facility operators submit a detailed layout of the facility site and its location to APHIS. APHIS would evaluate plant health risks based on the proposed location and layout of the facility site before a facility is approved. APHIS would only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from the port of entry or points of origin in the United States. Proposed paragraph (b)(1)(ii) of § 305.6 provides that the State government of the Southern or Western State in which the facility would be located would also have to concur in writing with the location of the cold treatment facility; if it does not concur, the State government must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, then APHIS and the State would need to agree on a strategy to resolve such risks before APHIS approved the facility. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

Under this proposal, paragraphs (b)(1)(iii) and (b)(1)(iv) of § 305.6 would provide, respectively, that untreated articles may not be removed from their packaging prior to treatment under any circumstances, and that facilities must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility were unable to properly treat a shipment. Alternatively, facilities could be approved to apply alternative treatments, if available, such as fumigation with methyl bromide or irradiation.

Proposed paragraph (b)(1)(v) of § 305.6 would allow a cold treatment facility to treat only those articles that are approved by APHIS for treatment at that facility. If, during the approval process for regulated articles, APHIS determines that additional safeguards (such as trapping for specific pests using specific lures, inspection for any pests of concern not mitigated by cold treatment or to monitor pest population in the consignment, or applying required treatments in addition to cold treatment) are deemed necessary during transport or while at a specific cold treatment facility, the compliance agreement for the facility would be amended accordingly.

Under proposed paragraph (b)(1)(vi) of § 305.6, APHIS, the importer, and the cold treatment facility would need to agree on arrangements for treatment before the departure of a consignment from its country of origin or point of origin in the United States. This would ensure that untreated shipments of regulated articles arriving at the facility would not have to wait for an extended period of time for cold treatment. The expeditious treatment of the articles would minimize the risk of pests of concern maturing in fruits, vegetables, or other articles. In addition, we are proposing that APHIS and the cold treatment facility would have to agree in advance about all parameters, such as time, routing, and conveyance, by which every consignment would move from the port of entry or points of origin in the United States to the cold treatment facility. In most instances, this would be determined by establishing the shortest route between the port of entry or points of origin in the United States and the cold treatment facility that does not include an area that contains host material for pests of concern during the time of year that the host material is most abundant in the region. This route would then be used at all times of the year, since an area that is free of host material during the time of year that it is most abundantly grown, would be unlikely to grow host material at any other time of year. This predetermined route would reduce the amount of time that a shipment would have to wait before undergoing cold treatment and would reduce the risk that any pests of concern in the shipments would come into contact with host material en route to the cold treatment facility. If APHIS and the cold treatment facility cannot reach agreement in advance on all parameters by which consignments would move from the port of entry or points of origin in the United States then no consignments may be moved to that facility until an agreement has been reached.

We are also proposing to require in paragraph (b)(1)(vii) of § 305.6 that the conveyance transporting the regulated article to the cold treatment facility would need to be refrigerated using motorized refrigeration equipment to a temperature that would minimize the mobility of the pests of concern for the article. Fruits and vegetables requiring cold treatment are typically transported in refrigerated conveyances in order to preserve freshness of the commodity and prevent development of toxins that may affect their flavor.

Proposed paragraph (b)(1)(viii) of § 305.6 would stipulate that the cold treatment facility would be required to apply all required post-treatment safeguards as required by the compliance agreement to provide phytosanitary protection (*e.g.,* larger consignments broken up into smaller boxes following treatment and those treated articles subsequently packaged in pest-proof containers per an agreement between the treatment facility and the importer) before releasing the articles to the importer or the importer's designated representative or before moving the articles interstate. Paragraph (b)(1)(ix) would require the facility to remain locked when not in operation. These requirements are intended to minimize the risk of cross-contamination between treated and untreated articles and to prevent unauthorized persons access to the facility, which may result in the unintended entry of pests of concern.

The current regulations for cold treatment facilities at the maritime ports of Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; and Hartsfield-Atlanta International Airport, Atlanta, GA, require blacklight or sticky paper to be used within the cold treatment facility and other trapping methods to be used within the 4 square miles surrounding the facility. Proposed paragraph (b)(1)(x) of § 305.6 requires, in addition, that the facility maintain and provide APHIS an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. APHIS will use this information to determine if any host material of concern is present. To help prevent establishment of pests in the unlikely event that they escape despite the required precautions, the presence of any host material within 4 square miles of the facility would then necessitate specific trapping or other pest monitoring activities to help prevent establishment of any escaped pests of concern, which would be funded by the facility and described in the compliance agreement. All trapping and pest monitoring activities would need to be approved by APHIS.

The cold treatment facility would also need to have a pest management plan within the facility, which would cover such topics as monitoring for pests in storage and treatment areas and the actions to be taken in the event of the detection of pests within the facility. Cold treatment facilities would also be required to comply with any additional requirements that APHIS might require for a particular facility based on local conditions and any other risk factors of concern. This could include inspection for certain pests for which cold treatment is not an approved treatment, such as mites and scales. Proposed paragraph (b)(1)(xi) of § 305.6 would require that facilities comply with any additional APHIS requirements including, but not limited to, the use of pest-proof packaging and container seals. Such additional requirements would be contained in a compliance agreement. Compliance agreements are required for all facilities in paragraph (f) of § 305.6, which we are proposing to amend as detailed below under the heading "Cold Treatment Facilities in All the United States."

We also propose to add language specifying the way in which domestically produced fruit would be safeguarded when moving interstate from areas within the United States that are quarantined for fruit flies. In proposed paragraph (b)(2) of § 305.6, we would stipulate that, for articles that are moved interstate from areas quarantined for fruit flies, cold treatment facilities would be permitted to be located within or outside of the quarantined area. If the articles are treated outside the quarantined area, they would have to be accompanied to the facility by a limited permit issued in accordance with 7 CFR 301.32–5(b) of our fruit fly regulations and must be moved in accordance with any safeguards determined appropriate by APHIS. These additions are necessary because the current cold treatment regulations do not address interstate movement and this addition would serve to clarify our requirements.

Cold Treatment Facilities in All the United States

In paragraph (a) of § 305.6, we are proposing to expand our requirements for initial facility certification and recertification. A prospective facility would only be certified if the Administrator determines that the location of that facility is operationally feasible insofar as the Federal agencies involved in its operation and oversight have adequate resources to conduct the necessary operations at the facility, that the pest risks can be managed at that location, and that the facility meets all criteria for approval. Facility recertification would continue to be required at 3 year intervals or at other times as determined by APHIS based on treatments performed, commodities handled, and operations conducted at the facility.

Currently, as part of the approval process for cold treatment facilities, APHIS considers whether a proposed cold treatment facility is located within the local commuting area for APHIS employees so that they will be able to perform the oversight and monitoring activities required by § 305.6. When imported articles are to be treated at a facility, APHIS also considers whether the facility is located within an area over which the U.S. Department of Homeland Security (DHS)[3] has customs authority for enforcement purposes. We are proposing to amend paragraph (e) of § 305.6, which contains requirements for monitoring and interagency agreements for cold treatment facilities, to require all cold treatment facilities to be located within the local commuting area for APHIS employees[4] for oversight and monitoring purposes. For facilities treating imported articles, we are also proposing that the location of the facility would have to be within an area over which DHS has customs authority for enforcement purposes.

The regulations in § 305.6(d)(15) currently stipulate that an inspector will sample and cut fruit from consignments that have been cold treated for Mediterranean fruit fly (Medfly) in order to monitor treatment effectiveness. We are proposing to expand the fruit cutting and inspection requirements in order to state that consignments treated for other fruit flies and pests of concern may be subject to sampling and cutting. This would create an extra level of phytosanitary security for cold treated shipments.

If the national plant protection organization cuts and inspects the commodity in the exporting country as part of a biometric sampling protocol that we have approved, however, we are proposing that we may waive this requirement. In such instances, inspection and cutting would be duplicative.

Paragraph (f) of § 305.6 currently requires that cold treatment facilities located in the United States must enter into a compliance agreement with APHIS. These compliance agreements set out requirements for equipment, temperature, circulation, and other operational requirements for performing cold treatment to ensure that treatments are administered properly. They also allow for inspection by APHIS in order to monitor compliance with those requirements. Paragraph (g) contains requirements for facilities located outside the United States, which may only operate under a bilateral workplan. A bilateral workplan may contain some of the same requirements as a domestic compliance agreement, with the potential addition of trust fund agreement information regarding payment of the salaries and expenses of APHIS employees on site. We are proposing to combine these requirements into a single paragraph that would set out the requirements that both domestic and foreign cold treatment facilities and importers would have to meet in order to enter into a compliance agreement with APHIS. We are also proposing to add language regarding compliance agreements required in association with articles moved interstate from Hawaii and the U.S. territories. These requirements are consistent with those required for importers shipping articles to irradiation facilities located in the southern United States and are necessary to ensure that consignments of fruits or vegetables are not diverted to any destination other than an approved treatment facility, to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival into the United States to the approved cold treatment facility, and to ensure that APHIS is aware of the time, route, and conveyance by which consignments will move to the treatment facility.

Fumigation Treatment and Compliance Agreements

We are proposing to add a section to the regulations concerning fumigation treatment found in § 305.5 to provide that both domestic and foreign fumigation treatment facilities and importers enter into a compliance agreement with APHIS, and agree to comply with any requirements deemed necessary by the Administrator. Although we currently enter into compliance agreements with domestic chemical treatment facilities and have done so for more than 20 years, the addition of a requirement for compliance agreements to the fumigation treatment regulations will add a degree of enforceability to the terms of those agreements in addition to codifying our existing practices.

We are also proposing to add a requirement concerning establishment of a compliance agreement, or an equivalent agreement such as a workplan agreement, for those fumigation treatment facilities located outside the United States. Such facilities had not been previously required to sign such an agreement to treat articles imported into the United States under the fumigation treatment regulations. The proposed requirements would be identical to those found in the sections of the treatment regulations concerning cold treatment and heat treatment, and would be added in a new paragraph (c) in § 305.5.

Irradiation Treatment and State and Facility Compliance

We are proposing to harmonize the language concerning State compliance with irradiation treatment facility establishment and facility agreements found in § 305.9 with the proposed language concerning this compliance in the cold treatment regulations.

Section 305.9(a)(1)(ii) states that the government of the State in which the facility is to be located must concur in writing with the establishment of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, APHIS and the State will agree on a strategy to resolve the pest risk concerns prior to APHIS approval. We would add that, if the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

Section 305.9(a)(1)(vi) states that APHIS and the irradiation treatment facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. We are proposing to clarify that if APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

Definitions

We are also proposing to add a definition for "treatment facility" as follows to the regulations in § 305.1: "Any APHIS-certified place, warehouse, or approved enclosure where a treatment is conducted to mitigate a plant pest." This is intended to provide clarity and guidance in the regulations as the term is included in the proposed additions to the regulations.

Treatment Schedules

Finally, the current regulations in § 305.2, paragraph (b), state that approved treatment schedules are set out in the PPQ Treatment Manual.

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[3] The U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force.

[4] Commuting area would be determined by contacting the local APHIS Plant Protection and Quarantine office, State Plant Health Director, located in each State, Eastern Regional Office, or Western Regional Office.

Section 305.3 sets forth a process for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. Paragraph (a)(1) provides that removal of a treatment schedule is subject to public comment.

We are proposing to remove a cold treatment schedule from the PPQ Treatment Manual. Treatment schedule T107-f was authorized for use on shipments of Ya pears (*Pyrus* x *bretscheideri*) from APHIS-authorized areas within Shandong Province, China, in order to provide phytosanitary protection against the Oriental fruit fly (*Bactrocera dorsalis*). Based on Oriental fruit fly trapping results and climatological and biological considerations, we have determined that cold treatment of Ya pears is no longer necessary and are therefore proposing to remove the treatment schedule. All other requirements regarding the importation of Ya pears would remain in place.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

We are proposing to establish general criteria for new cold treatment facilities in the Southern and Western United States. These general criteria would be supplemented as necessary by additional measures, which would be described in the facility's compliance agreement, based on pests of concern associated with specific regulated articles to be treated at the facility and the location of the specific facility.

We do not anticipate that the proposed rule would have an economic impact, since it would simply set forth the general criteria, not approve any new facilities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2013–0081. Please send a copy of your comments to: (1) APHIS, using one of the methods described under **ADDRESSES** at the beginning of this document, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

APHIS is proposing to amend the phytosanitary treatment regulations to establish generic criteria that would allow for the approval of new cold treatment facilities in the Southern and Western States of the United States. These criteria, if met, would allow APHIS to approve new cold treatment facilities without rulemaking and facilitate the importation of fruit requiring cold treatment while continuing to provide protection against the introduction of pests of concern into the United States. APHIS is also proposing to amend the fruit cutting and inspection requirements in the cold treatment regulations in order to expand cutting and inspection to commodities that have been treated for a wider variety of pests of concern. This action would provide for a greater degree of phytosanitary protection. Finally, APHIS is proposing to add requirements concerning the establishment of compliance agreements for those entities that operate fumigation facilities. This action would serve to codify and make enforceable existing procedures concerning compliance agreements for these facilities.

Implementing this rule will require the completion of compliance agreements, facility certification, detailed layouts of facilities and maps of the surrounding areas, State concurrence letters, limited permits, and contingency plans.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.5 hours per response.

Respondents: NPPO, facility operators, importers, and State governments.

Estimated annual number of respondents: 15.

Estimated annual number of responses per respondent: 3.

Estimated annual number of responses: 42.

Estimated total annual burden on respondents: 21 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

List of Subjects in 7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 305 as follows:

PART 305—PHYTOSANITARY TREATMENTS

■ 1. The authority citation for part 305 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 305.1 is amended by adding, in alphabetical order, a definition for *treatment facility* to read as follows:

§ 305.1 Definitions.

* * * * *

Treatment facility. Any APHIS-certified place, warehouse, or approved enclosure where a treatment is conducted to mitigate a plant pest.

* * * * *

■ 3. Section 305.5 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c).

The addition reads as follows:

§ 305.5 Chemical treatment requirements.

* * * * *

(c) *Compliance agreements.* Any person who conducts a fumigation or operates a facility where fumigation is conducted for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) *Fumigation treatment facilities treating imported articles.* (i) *Compliance agreements with importers and facility operators for fumigation in the United States.* If fumigation treatment of imported articles is conducted in the United States, both the importer and the fumigation treatment facility operator or the person who conducts fumigation must sign compliance agreements with APHIS. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival to the fumigation treatment facility in the United States. In the facility compliance agreement, the fumigation facility operator or the person who conducts fumigation must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(ii) *Compliance agreements with fumigation treatment facilities outside the United States.* If fumigation treatment of imported articles is conducted outside the United States, the fumigation treatment facility operator or the person who conducts the fumigation must sign a compliance agreement or an equivalent agreement with APHIS and the national plant protection organization (NPPO) of the country in which the facility is located. In this agreement, the fumigation treatment facility operator or person conducting the fumigation must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

(2) *Fumigation treatment facilities treating articles moved interstate from Hawaii and U.S. territories.* Fumigation treatment facilities treating articles moved interstate from Hawaii and U.S. territories must complete a compliance agreement with APHIS as provided in § 318.13–3(d) of this chapter.

(3) *Fumigation treatment facilities treating articles moved interstate from areas quarantined for fruit flies.* Fumigation treatment facilities treating articles moved interstate from areas quarantined for fruit flies must complete a compliance agreement with APHIS as provided in § 301.32–6 of this chapter.

(4) *Fumigation treatment facilities treating articles moved interstate from areas quarantined for Asian citrus psyllid.* Fumigation treatment facilities treating articles moved interstate from areas quarantined only for Asian citrus psyllid, and not for citrus greening, must complete a compliance agreement with APHIS as provided in § 301.76–8 of this chapter.

* * * * *

■ 4. Section 305.6 is amended as follows:

■ a. In the introductory text of paragraph (a), by adding two new sentences before the last sentence.

■ b. By redesignating paragraph (a)(2) as paragraph (a)(3).

■ c. By adding new paragraph (a)(2).

■ d. By revising paragraph (b).

■ e. By revising paragraph (d)(15).

■ f. In paragraph (e), by adding two new sentences after the last sentence.

■ g. By revising paragraph (f).

■ h. By removing paragraphs (g) and (h).

The additions and revisions read as follows:

§ 305.6 Cold treatment requirements.

(a) * * * A facility will only be certified or recertified if the Administrator determines that the location of the facility is such that those Federal agencies involved in its operation and oversight have adequate resources to conduct the necessary operations at the facility, that the pest risks can be managed at that location, and that the facility meets all criteria for approval. Other agencies that have regulatory oversight and requirements must concur in writing with the establishment of the facility prior to APHIS approval. * * *

* * * * *

(2) Be capable of preventing the escape and spread of pests while regulated articles are at the facility; and

* * * * *

(b)(1) *Location of facilities.* Where certified cold treatment facilities are available, an approved cold treatment may be conducted for any imported regulated article either prior to shipment to the United States or in the United States. For any regulated article moved interstate from Hawaii or U.S. territories, cold treatment may be conducted either prior to movement to the mainland United States or in the mainland United States. Cold treatment facilities may be located in any State on the mainland United States. For cold treatment facilities located in the area south of 39° latitude and west of 104° longitude, the following additional conditions must be met:

(i) Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from the port of entry or points of origin in the United States.

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

(iii) Untreated articles may not be removed from their packaging prior to treatment under any circumstances.

(iv) The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility is unable to properly treat a shipment.

(v) The facility may only treat articles approved by APHIS for treatment at the facility. Approved articles will be listed in the compliance agreement required in paragraph (f) of this section.

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

(vii) Regulated articles must be conveyed to the facility in a refrigerated (via motorized refrigeration equipment) conveyance at a temperature that minimizes the mobility of the pests of concern for the article.

(viii) The facility must apply all post-treatment safeguards required for certification under paragraph (a) of this section before releasing the articles.

(ix) The facility must remain locked when not in operation.

(x) The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. Proximity of host material to the facility will necessitate trapping or other pest monitoring activities, funded by the facility, to help prevent establishment of any escaped pests of concern, as approved by APHIS; these activities will be listed in the compliance agreement required in paragraph (f) of this section. The treatment facility must have a pest management plan within the facility.

(xi) The facility must comply with any additional requirements including, but not limited to, the use of pest-proof packaging and container seals, that APHIS may require to prevent the escape of plant pests during transport to and from the cold treatment facility itself, for a particular facility based on local conditions, and for any other risk factors of concern. These activities will be listed in the compliance agreement required in paragraph (f) of this section.

(2) For articles that are moved interstate from areas quarantined for fruit flies, cold treatment facilities may be located either within or outside of the quarantined area. If the articles are treated outside the quarantined area, they must be accompanied to the facility by a limited permit issued in accordance with § 301.32–5(b) of this chapter and must be moved in accordance with any safeguards determined to be appropriate by APHIS.

* * * * *

(d) * * *

(15) An inspector will sample and cut fruit from each consignment after it has been cold treated to monitor treatment effectiveness. If a single live pest of concern in any stage of development is found, the consignment will be held until an investigation is completed and appropriate remedial actions have been implemented. If APHIS determines at any time that the safeguards contained in this section do not appear to be effective against the pests of concern, APHIS may suspend the importation of fruits from the originating country and conduct an investigation into the cause of the deficiency. APHIS may waive the sampling and cutting requirement of this paragraph, provided that the national plant protection organization of the exporting country has conducted such sampling and cutting in the exporting country as part of a biometric sampling protocol approved by APHIS.

* * * * *

(e) * * * Facilities must be located within the local commuting area for APHIS employees for inspection purposes. Facilities treating imported articles must also be located within an area over which the U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force.

(f) *Compliance agreements.* Any person who operates a facility where cold treatment is conducted for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) *Compliance agreements with importers and facility operators for cold treatment in the United States.* If cold treatment of imported articles is conducted in the United States, both the importer and the operator of the cold treatment facility or the person who conducts the cold treatment must sign compliance agreements with APHIS. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival to the cold treatment facility in the United States. In the facility compliance agreement, the facility operator or person conducting the cold treatment, must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(2) *Compliance agreements with cold treatment facilities outside the United States.* If cold treatment of imported articles is conducted outside the United States, the operator of the cold treatment facility must sign a compliance agreement or an equivalent agreement with APHIS and the NPPO of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and inform the Administrator of any noncompliance.

(3) *Cold treatment facilities treating articles moved interstate from Hawaii and U.S. territories.* Cold treatment facilities treating articles moved interstate from Hawaii and the U.S. territories must complete a compliance agreement with APHIS as provided in § 318.13–3(d) of this chapter.

■ 5. Section 305.9 is amended:

■ a. By revising paragraph (a)(1)(ii).

■ b. By revising paragraph (a)(1)(vi).

The revisions read as follows:

§ 305.9 Irradiation treatment requirements.

* * * * *

(a) * * *

(1) * * *

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

* * * * *

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States.

APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

* * * * *

Done in Washington, DC, this 24th day of June 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–15568 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1260

[No. AMS–LPS–15–0084]

Amendment to the Beef Promotion and Research Rules and Regulations; Withdrawal

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Withdrawal of proposed rule.

SUMMARY: This document informs the public that the Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA) is withdrawing the proposed rule published in the **Federal Register** (81 FR 14022) on March 16, 2016, regarding the Beef Promotion and Research Order (Order) established under the Beef Promotion and Research Act of 1985 (Act). The proposed rule is being withdrawn because of an error noted in the formula determining the assessment rate on imported veal carcass weight and to provide the calculation to establish the assessment rate on importer veal and veal products.

DATES: The proposed rule published on March 26, 2016 (81 FR 14022), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Michael Dinkel, Agricultural Marketing Specialist; Research and Promotion Division, Room 2610–S; Livestock, Poultry, and Seed Program; AMS, USDA, STOP 0249; 1400 Independence Avenue SW., Washington, DC 20250–0249; facsimile 202/720–1125; telephone 301/352–7497, or by email at *Michael.Dinkel@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Act authorized the establishment of a national beef promotion and research program. The final Order was published in the **Federal Register** (51 FR 21632) on July 18, 1986, and the collection of assessments began on October 1, 1986. The program is administered by the Cattlemen's Beef Promotion and Research Board, appointed by the Secretary of Agriculture from industry nominations, and composed of 100 cattle producers and importers. The program is funded by a $1-per-head assessment on producer marketing of cattle in the U.S. and on imported cattle, as well as an equivalent amount on imported beef and beef products. The U.S. Customs and Border Protection Service collects assessments from importers.

On March 16, 2016, AMS published in the **Federal Register** (81 FR 14022) a proposed rule amending the Order established under the Act to add Harmonized Tariff Schedule (HTS) codes for veal and veal products not currently covered under the Order and to update the carcass weight for imported veal carcasses used to determine the assessment rate for imported veal and veal products.

Following publication, AMS discovered an error in the carcass weight of imported veal carcasses used to determine the assessment rate for imported veal and veal products. The correct weight used to calculate the assessment rate was published as 151 pounds, but the correct weight is 154 pounds. In addition, the industry recently requested the formula for how the assessment rate for imported veal and veal products is calculated. As a result of both the discovered error and the industry request, AMS is withdrawing the proposed rule and will publish a new proposed rule with the corrected carcass weight and formula.

Dated: June 17, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–14823 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 460

Draft Environmental Assessment for Notice of Proposed Rulemaking, "Energy Conservation Standards for Manufactured Housing" With Request for Information on Impacts to Indoor Air Quality

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

ACTION: Notice of availability; request for public comment, and request for information.

SUMMARY: Section 413 of the Energy Independence and Security Act of 2007 (EISA) directs the U.S. Department of Energy (DOE) to establish energy conservation standards for manufactured housing. Section 413 further directs DOE to base its energy conservation standards on the most recent version of the International Energy Conservation Code (IECC) and any supplements to that document, except where DOE finds that the IECC is not cost effective or where a more stringent standard would be more cost effective, based on the impact of the IECC on the purchase price of manufactured housing and on total lifecycle construction and operating costs. On June 17, 2016, DOE published a notice of proposed rulemaking in the **Federal Register** pertaining to energy efficiency for manufactured housing.

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE Office of Energy Efficiency and Renewable Energy (EERE) has prepared a draft environmental assessment (EA) to evaluate the environmental impacts of this proposed action. DOE is seeking public comment on the environmental issues addressed in the EA. In conjunction with issuance of this draft EA for public review and comment, DOE is issuing a request for information that will help it analyze potential impacts on indoor air quality (IAQ) from the proposed energy conservation standards, in particular sealing manufactured homes tighter.

DATES: Comments regarding this draft EA and/or information on IAQ must be received on or before August 15, 2016.

ADDRESSES: Written comments should be sent to Roak Parker at U.S. Department of Energy, 15013 Denver West Parkway, Golden, CO 80401, or by email at *RulemakingEAs@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the draft environmental assessment should be directed to Roak

Parker at *RulemakingEAs@ee.doe.gov* or by telephone at (240) 562–1645. The draft environmental assessment also is available for viewing in the Golden Public Reading Room at: *www.energy.gov/node/1840021*.

SUPPLEMENTARY INFORMATION: DOE has published a notice of proposed rulemaking in the **Federal Register** pertaining to energy efficiency for manufactured housing. 81 FR 39756 (June 17, 2016). Pursuant to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), DOE EERE has prepared a draft environmental assessment (EA) to evaluate the environmental impacts of this proposed action. DOE is seeking public comment on the environmental issues addressed in the EA. In conjunction with issuance of this draft EA for public review and comment, DOE is issuing a request for information that will help it analyze potential impacts on indoor air quality (IAQ) from the proposed energy conservation standards, in particular sealing manufactured homes tighter.

Statutory Authority: National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*).

Issued in Golden, CO, on June 21, 2016.

Robin L. Sweeney,

Director, Environment, Safety and Health Office, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 2016–15328 Filed 6–29–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF COMMERCE

Bureau of the Census

15 CFR Chapter I

[Docket Number 160526465–6465–01]

Proposed 2020 Census Residence Criteria and Residence Situations

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Proposed criteria and request for comment.

SUMMARY: The Bureau of the Census (U.S. Census Bureau) is providing notification and requesting comment on the proposed "2020 Census Residence Rule and Residence Situations." In addition, this document contains a summary of comments received in response to the May 20, 2015, **Federal Register** document, as well as the Census Bureau's responses to those comments. The residence criteria are used to determine where people are counted during each decennial census.

included with the criteria to illustrate how the criteria are applied.

DATES: To ensure consideration, comments must be received by August 1, 2016.

ADDRESSES: Direct all written comments regarding the proposed "2020 Census Residence Rule and Residence Situations" to Karen Humes, Chief, Population Division, U.S. Census Bureau, Room 6H174, Washington, DC 20233; or Email [*POP.2020.Residence.Rule@census.gov*].

FOR FURTHER INFORMATION CONTACT: Population and Housing Programs Branch, U.S. Census Bureau, 6H185, Washington, DC 20233, telephone (301) 763–2381; or Email [*POP.2020.Residence.Rule@census.gov*].

SUPPLEMENTARY INFORMATION:

A. Background

The U.S. Census Bureau is committed to counting every person in the 2020 Census once, only once, and in the right place. The fundamental reason that the decennial census is conducted is to fulfill the Constitutional requirement (Article I, Section 2) to apportion the seats in the U.S. House of Representatives among the states. Thus, for a fair and equitable apportionment, it is crucial that the Census Bureau counts everyone in the right place during the decennial census.

The residence criteria are used to determine where people are counted during each decennial census. Specific residence situations are included with the criteria to illustrate how the criteria are applied.

1. The Concept of Usual Residence

The Census Act of 1790 established the concept of "usual residence" as the main principle in determining where people were to be counted, and this concept has been followed in all subsequent censuses. "Usual residence" has been defined as the place where a person lives and sleeps most of the time. This place is not necessarily the same as a person's voting residence or legal residence.

Determining usual residence is straightforward for most people. However, given our nation's wide diversity in types of living arrangements, the concept of usual residence has a variety of applications. Some examples include people experiencing homelessness, people with a seasonal/second residence, people in prisons, people in the process of moving, people in hospitals, children in shared custody arrangements, college personnel, and people who live in workers' dormitories.

Applying the usual residence concept to real living situations means that people will not always be counted at the place where they happen to be staying on Census Day (April 1, 2020) or at the time they complete their census questionnaire. For example, some of the ways that the Census Bureau applies the concept of usual residence include the following:

- People who are away from their usual residence while on vacation or on a business trip on Census Day are counted at their usual residence.
- People who live at more than one residence during the week, month, or year are counted at the place where they live most of the time.
- People without a usual residence are counted where they are staying on Census Day.
- People in certain types of group facilities [1] on Census Day are counted at the group facility.

2. Reviewing the "2020 Census Residence Rule and Residence Situations"

Every decade, the Census Bureau undertakes a review of the "Residence Rule and Residence Situations" to ensure that the concept of usual residence is interpreted and applied as intended in the decennial census, and that these interpretations are consistent with the intent of the Census Act of 1790, which was authored by a Congress that included many of the framers of the U.S. Constitution and directed that people were to be counted at their usual residence. This review also serves as an opportunity to identify new or changing living situations resulting from societal change, and to create or revise the guidance regarding those situations in a way that is consistent with the concept of usual residence.

This decade, as part of the review, the Census Bureau requested public comment on the "2010 Census Residence Rule and Residence Situations" through the **Federal Register** (80 FR 28950) on May 20, 2015, to allow the public to recommend any changes they would like to be considered for the 2020 Census. The Census Bureau received 252 comment submission letters or emails that contained 262 total comments. (Some comment submissions included comments or suggestions on more than one residence situation.) A summary of these comments and the Census Bureau's responses are included in section B of this document.

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[1] In this document, "group facilities" (referred to also as "group quarters" (GQ)) are defined as places where people live or stay in group living arrangements, which are owned or managed by an entity or organization providing housing and/or

In addition to the Census Bureau's responses to comments that are described in section B of this document, section C provides a summary of each of the proposed changes to where people would be counted in the 2020 Census compared to the 2010 Census. These proposed changes are based on the consideration of public comments received, as well as an internal review of the criteria and situations.

The Census Bureau is requesting public comment on the proposed "2020 Census Residence Rule and Residence Situations", as listed in section D of this document. The Census Bureau is requesting public comment on the proposed "2020 Census Residence Rule and Residence Situations," as listed in section D of this document. The Census Bureau anticipates publishing the final "2020 Census Residence Rule and Residence Situations" by the end of 2016. At that time, the Census Bureau will also respond to the comments received regarding the proposed "2020 Census Residence Rule and Residence Situations."

B. Summary of Comments Received in Response to a Review of the "2010 Census Residence Rule and Residence Situations"

On May 20, 2015, the Census Bureau published a document in the **Federal Register** asking for public comment on the "2010 Census Residence Rule and Residence Situations." Of the 262 comments received, 162 pertained to where prisoners[2] are counted, and 87 pertained to where military personnel overseas are counted. Two comments pertained to people in group homes for juveniles, two comments to people in residential treatment centers for juveniles, and one comment to students in boarding schools. Also, one comment pertained to the residence criteria, and one comment to each of four other residence situations: Visitors on Census Day, people who live in more than one place, people without a usual residence, and nonrelatives of the householder. Finally, three comments covered broader issues: One pertaining to how the residence criteria and situations are communicated, one pertaining to how field staff is trained on the residence criteria and situations, and one on how alternative addresses are collected from certain types of group facilities.

1. Comments on Prisoners

Of the 162 comments pertaining to prisoners, 156 suggested that prisoners should be counted at their home or pre-incarceration address. The rationales included in these comments were as follows:

- Counting prisoners at the prison inaccurately represents the prisoners' home communities, inflates the political power of the area where the prison is located, and deflates the political power in the prisoners' home communities. This distorts the redistricting process.
- Counting prisoners away from their home address goes against the principle of equal representation.
- The current residence criteria for prisoners is inconsistent with some states' laws regarding residency for elections.
- The "usual residence" concept itself should change, as it relates to incarcerated persons, because the tremendous increase in the number of incarcerated people in the last 30 years, and the Supreme Court's support of equal representation, warrants a change in the interpretation of the concept of "usual residence."
- Prisoners do not interact or participate in the civic life of the community where they are incarcerated, are there involuntarily, and generally do not plan to remain in that community upon their release.
- One comment stated that inmates in local jails who are awaiting trial are presumed innocent, and therefore should not be counted at the jail.

Six comments were in support of the 2010 practice of counting prisoners at the prison, stating that adjusting prisoners' locations would be difficult, expensive, add unneeded complexity, and would be prone to inaccuracy. Of the six comments in support of counting prisoners at the prison, one mentioned a concern that adjusting the prisoners' locations could disenfranchise minorities in rural areas, and four said that changing the current practice could open the door to future census population count adjustments motivated by political gain.

Census Bureau Response: The Census Bureau has determined that the practice of counting prisoners at the correctional facility for the 2020 Census would be consistent with the concept of usual residence, as established by the Census Act of 1790. As noted in section A.1 of this document, "usual residence" is defined as the place where a person lives and sleeps most of the time, which is not always the same as their legal residence, voting residence, or where they prefer to be counted. Therefore, counting prisoners anywhere other than the facility would violate the concept of usual residence, since the majority of people in prisons live and sleep most of the time at the prison.

States are responsible for legislative redistricting. The Census Bureau works closely with the states and recognizes that some states have decided, or may decide in the future, to 'move' their prisoner population back to the prisoners' pre-incarceration addresses for redistricting and other purposes. Therefore, following the 2020 Census, the Census Bureau plans to offer a product that states can request, in order to assist them in their goals of reallocating their own prisoner population counts. Any state that requests this product will be required to submit a data file (indicating where each prisoner was incarcerated on Census Day, as well as their pre-incarceration address) in a specified format. The Census Bureau will review the submitted file and, if it includes the necessary data, provide a product that contains supplemental information the state can use to construct alternative within-state tabulations for its own purposes. However, the Census Bureau will not use the information in this product to make any changes to the official decennial census counts.

The Census Bureau also plans to provide group quarters data after the 2020 Census sooner than it was provided after the 2010 Census. For the 2010 Census, the Census Bureau released the *Advance Group Quarters Summary File* showing the seven major types of group quarters, including correctional facilities for adults and juvenile facilities. This early[3] release of data on the group quarters population was beneficial to many data users, including those in the redistricting community who must consider whether to include or exclude certain populations when redrawing boundaries as a result of state legislation. The Census Bureau is planning to incorporate similar group quarters information in the standard *Redistricting Data (Pub. L. 94–171) Summary File* for 2020.

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[2] The majority of comments received on this topic used the terms 'prisoner,' 'incarcerated,' or 'inmate.' Although the terminology is not exactly what is used in the residence rule documentation, the context of the comments suggests that they apply to people in federal and state prisons (GQ type 102 and 103), local jails and other municipal confinement facilities (GQ type 104), and possibly federal detention centers (GQ type 101). References in this document to "prisons," or "prisoners," should be interpreted as referring to all of these GQ

[3] The *Advance Group Quarters Summary File* was released on April 20, 2011, which was earlier than when that GQ data was originally planned to be released in the *Summary File 1* that was released on June 16—August 25, 2011. The earlier release made it easier to use these GQ data in conjunction with the *Redistricting Data (Pub. L. 94–171) Summary File*, which was released on February 3–

2. Comments on the Military Overseas

Of the 87 comments received pertaining to the military overseas, all suggested that the Census Bureau treat military personnel who are temporarily *deployed* overseas on a short-term basis differently than military personnel who are *stationed* overseas on a more long-term basis. More specifically, these comments suggested that military personnel who are deployed overseas should be counted at their home base or port. The commenters also suggested that the Census Bureau work with military bases to locate more accurate administrative records for counting deployed military and use administrative records to provide socioeconomic information on the deployed military.

In the 2010 Census, the Census Bureau counted all military personnel deployed or stationed overseas in their 'home of record' state for apportionment purposes only. Their home of record was provided by the Department of Defense (DOD),[4] and those state counts were added to the state population counts that were used to calculate the apportionment of seats for each state in the U.S. House of Representatives.

The commenters not only indicated that they want military personnel deployed overseas to be counted at their "usual residence," "last duty station," or "home base or port," (which are inferred to mean the same thing), but also that they want the Census Bureau to collect all decennial census demographic data on these personnel and include them in the local community-level resident population counts, rather than only using a basic population count of them for determining the state-level apportionment counts. For example, many comments referred to the need for counting deployed military in the communities where they usually reside, because doing otherwise "produces flawed data that harms funding and planning in military communities." Another comment referred to ensuring "communities have the needed resources to support these soldiers and their families." These and other comments may refer to local-level planning and funding that is normally determined using the Census resident population data (available down to the block level) and not the apportionment counts, which are only available at the state level.

To support the argument for counting deployed military overseas at their usual residence in the United States, one of the 87 commenters compared how the Census Bureau counts U.S. military personnel deployed to a land-based location overseas versus U.S. military personnel on U.S. military vessels with a U.S. homeport. The "2010 Census Residence Rule and Residence Situations" stated that the latter are "counted at the onshore U.S. residence where they live and sleep most of the time. If they have no onshore U.S. residence, they are counted at their vessel's homeport." The commenter argued that this is inconsistent with how the Census Bureau has counted military personnel who are deployed to a land-based location overseas (while stationed at a location in the United States), and asked that all branches of service be treated the same and counted at their residence or home base/port.

Census Bureau Response: The Census Bureau has determined that there is a distinction between personnel who are *deployed* overseas and those who are *stationed* or *assigned* overseas. Deployments are typically short in duration, and the deployed personnel will be returning to their usual residence where they are stationed or assigned in the United States after their temporary deployment ends. Personnel stationed or assigned overseas generally remain overseas for longer periods of time, and often do not return to the previous stateside location from which they left. Therefore, counting deployed personnel at their usual residence in the United States follows the standard interpretation of the residence criteria to count people at their usual residence if they are temporarily away for work purposes. This change would provide consistency with how the Census Bureau counts U.S. military personnel on U.S. military vessels.

Based on the considerations described in the previous paragraph, for the 2020 Census, the Census Bureau proposes using administrative data from the DOD to count deployed personnel at their usual residence in the United States.[5] The Census Bureau would continue to count military and civilian employees of the U.S. Government who are stationed or assigned outside the United States, and their dependents living with them, in their home state, for apportionment purposes only, using administrative data provided by the DOD and the other federal agencies that employ them.

3. Comments on Group Homes for Juveniles and Residential Treatment Centers for Juveniles

Two comments pertained to group homes for juveniles and two comments to residential treatment centers for juveniles. All four of the comments supported counting the juveniles in these situations at their "household residence." One of the commenters on the group homes and one of the commenters on the residential treatment centers further stated that the juveniles should only be counted at their household residence if it is in the same state as the facility. If the residence is not in the same state, these two commenters stated that the juvenile should be counted at the facility. All four commenters argued that counting juveniles at the facility inflates the political power of the area where the facility is located and dilutes the representation of the juveniles' home communities.

Census Bureau Response: The Census Bureau reviewed where juveniles in these types of facilities are counted, based on the concept of usual residence. Most juveniles living in group homes are there for long periods of time and do not have a usual home elsewhere. The group home is where they live and sleep most of the time, so that is their usual residence. Conversely, most people in residential treatment centers for juveniles only stay at the facility temporarily and often have a usual home elsewhere that they return to after treatment is completed.

Based on the considerations described in the previous paragraph, the Census Bureau has determined that the practice of counting people in group homes for juveniles at the facility is consistent with the concept of usual residence. However, for the 2020 Census, the Census Bureau proposes to count people in residential treatment centers for juveniles at the residence where they live and sleep most of the time. If they do not have a usual home elsewhere, they would be counted at the facility.

4. Comment on Boarding Schools

One of the comments received was related to boarding schools. The commenter suggested applying the current guidance for students attending college to students attending boarding schools. In the past, students at boarding schools were counted at their parental home, while college students living away from their parental home while attending school were counted at the on-campus or off-campus residence where they lived and slept most of the time. The commenter noted that for foreign students attending boarding school, the school is their usual residence most of the year, and their parents live overseas. Therefore, these students likely were not counted under the 2010 guidance, even though they reside in the United States most of the year, because they do not have a parental home in the United States.

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[4] Home of record is generally the permanent home of the person at the time of entry or re-enlistment into the Armed Forces, as included on personnel files. If home of record information was not available for a person, the DOD used the person's "legal residence" (the residence a member declares for state income tax withholding purposes), or thirdly, "last duty station," to assign a home state.

[5] The ability to successfully integrate the DOD data on deployed personnel into the resident population counts must be evaluated and confirmed prior to the 2020 Census.

Census Bureau Response: The Census Bureau has historically counted boarding school students at their parental home, and has determined that it will continue doing so because of the students' age and dependency on their parents, and the likelihood that they would return to their parents' residence when they are not attending their boarding school (*e.g.,* weekends, summer/winter breaks, and when they stop attending the school).

5. Comments on Specific Wording of the "Residence Rule and Residence Situations"

One letter commented on the specific wording of the residence criteria and four residence situations. The letter focused on people who experience homelessness in nontraditional ways, avoid shelters, and instead stay with family, friends, or acquaintances.

(a) Residence Criteria

The comment was to add a fourth bullet (in addition to the three bullets that we already use to present the three main principles of the residence criteria, as shown in section D of this document) with language to make it clear where people experiencing homelessness, who are not in a shelter or facility, are counted.

Census Bureau Response: The Census Bureau has determined that the current wording of the residence criteria will be retained, because they are purposely written to broadly encapsulate all residence situations in a succinct way, and it is consistent with the requirement to count people at their usual residence, as originally prescribed by the Census Act of 1790. However, in section B.5.d of this document, the Census Bureau proposes an addition to the residence situations in order to provide more clarity on where people who are experiencing homelessness are counted.

(b) Visitors on Census Day

The commenter suggested eliminating the "Visitors on Census Day" residence situation and merging it into the "People Away From Their Usual Residence on Census Day" situation. The commenter was concerned that the way the situation was described in the 2010 documentation implied that that 'visitors' had another home to return to, which is not the case for visitors who are experiencing homelessness.

Census Bureau Response: The Census Bureau has determined that it will retain the separate "Visitors on Census Day" situation, but proposes removing the phrase "who will return to their usual residence" from the description. Additionally, the following sentence would be added to the end of the situation wording to further clarify that not all visitors have another home to return to: "If they do not have a usual residence to return to, they are counted where they are staying on Census Day."

(c) People Who Live in More Than One Place

This commenter also suggested changing the 2010 wording for the category title "People Who Live in More Than One Place" to "People With Multiple Residences." The examples in this category were not intended to address people experiencing homelessness. However, the commenter noted that people experiencing homelessness might stay in a different place from night to night, and therefore could also be interpreted as "People Who Live in More Than One Place."

Census Bureau Response: The Census Bureau was concerned that the commenter's suggested category title of "People with Multiple Residences," might also wrongly be interpreted as applying only to people who *own* multiple residences. Therefore, the Census Bureau proposes to change the category title to "People Who Live or Stay in More Than One Place."

(d) People Without a Usual Residence

The commenter also suggested adding a residence situation for "couch-surfers, youth experiencing homelessness, or other people staying in your residence for short or indefinite periods of time" to the "People Without a Usual Residence" category. The commenter believed that the examples included in this category in 2010 only addressed the more typical conception of homelessness (*e.g.,* people at soup kitchens or at non-sheltered outdoor locations), which does not align with how many other people experience homelessness in less recognized ways.

Census Bureau Response: The Census Bureau proposes to add a residence situation description to a new category called "People in Shelters and People Experiencing Homelessness," which clarifies where people are counted if they are experiencing homelessness and staying with friends or other people for short or indefinite periods of time (see section D.21.f of this document for exact wording).

(e) Nonrelatives of the Householder

Finally, the commenter suggested adding the same new situation, "couch-surfers, youth experiencing homelessness, or other people staying in your residence for short or indefinite periods of time" to the "Nonrelatives of the Householder" category.

Census Bureau Response: The Census Bureau proposes to address this comment by adding a situation for "Other nonrelatives, such as friends" to this category. Additionally, the Census Bureau proposes changing the title of this category from "Nonrelatives of the Householder" to "Relatives and Nonrelatives" and adding some situations that address relatives frequently missed or counted in the wrong place during the Census.

6. Other Comments

Three of the comments received did not address the residence criteria directly, nor did they address any particular residence situation.

(a) Clear Communication on the Residence Criteria and Residence Situations

One commenter suggested applying and communicating the residence criteria consistently across the country and cited the need for sound training for 2020 Census field workers, clear communication to 2020 Census partners and the public, and a "designated point-of-contact for residence determination."

Census Bureau Response: The Census Bureau is proposing many changes to the language and organization of the residence criteria and residence situations documentation to assist people in interpreting the criteria. However, issues related to training staff and the structure of specific 2020 Census operations are out of scope for this document.

(b) Questionnaire Content and Tabulations

One comment requested that the Census Bureau revisit the 2010 Individual Census Report (ICR) questions related to collecting information about where else the respondent might live or stay, and making it more consistent with the household Census questionnaire. A second comment encouraged the Census Bureau to produce summary file tabulations based on the answers to the "Does Person [X] sometimes live or stay somewhere else?" question, arguing that it would "help facilitate the best interpretation and use of decennial census data at the state and local level."

Census Bureau Response: These comments are out of scope for this document.

C. Proposed Changes to the "2020 Census Residence Rule and Residence Situations"

Most of the provisions regarding where people are counted, which are described in the proposed "2020 Census Residence Rule and Residence Situations" (section D of this document), would remain unchanged from those that were used for the 2010 Census. Therefore, this section C of this document will help the reader by providing a brief description of each of the proposed changes to where people are counted. All other changes to the proposed wording and/or presentation of the residence criteria and residence situations, as compared to how they were written for the 2010 Census, would be made in order to provide more clarity or to document provisions that were not explicitly stated in the past. (In other words, any differences between the 2010 and proposed 2020 Census residence criteria and situations documents that are not explained in section C of this document are only clarifications, rather than actual changes to the residence criteria or to where people would be counted in the decennial census.)

1. Federally Affiliated Overseas

(a) Military and Civilian Employees of the U.S. Government Who Are Deployed Overseas

For the 2010 Census, military and civilian employees of the U.S. Government who were deployed or stationed/assigned outside the United States (and their dependents living with them outside the United States) were counted (using administrative data) in their home state for apportionment purposes only. For the 2020 Census, there would be no change to how the Census Bureau counts the military and civilian Federal employees who are stationed or assigned outside the United States. However, there would be a change for deployed personnel, such that military and civilian employees of the U.S. Government who are deployed outside the United States (while stationed or assigned in the United States) would be counted at their usual residence in the United States and included in all 2020 Census data products (rather than only the apportionment counts). This change seeks to count deployed personnel in a way that is more consistent with the concept of usual residence, based on the short duration of most deployments and the fact that the personnel will return to their usual residence where they are stationed or assigned in the United States after their temporary deployment ends. More details about the considerations for this change can be found in section B of this document.

(b) Military and Civilian Employees of the U.S. Government Who Are Non-Citizens and Are Deployed or Stationed/Assigned Overseas

The "2010 Census Residence Rule and Residence Situations" were not clearly consistent regarding whether citizenship was a criterion for being included in the federally affiliated overseas population. The wording of the residence situation for military personnel overseas did not specify any citizenship criteria. However, the wording for Federal civilian employees overseas did specifically refer to U.S. citizens only, and the operational plan for the 2010 Census Federally Affiliated Overseas Count specified that both military and civilian employees of the U.S. Government who were non-citizens were excluded from the overseas counts, despite the fact that non-citizens were included in the stateside population.

After the 2010 Census, the operational assessment report for the Federally Affiliated Overseas Count recommended that the "2020 Census Residence Rule and Residence Situations" should make the guidance regarding citizenship clear and consistent not only across both military and civilian employees overseas, but also across the overseas and stateside populations. When considering such a change, the Census Bureau concluded that the rationales that are used for including the federally affiliated overseas population in the decennial census (*e.g.,* that they are temporarily away in service to our country's government) are equally applicable to citizens and non-citizens alike. Therefore, for the 2020 Census, military and civilian employees of the U.S. Government who are deployed or stationed/assigned overseas and are not U.S. citizens (but must be legal U.S. residents to meet the requirements for federal employment) would be included in the Federally Affiliated Overseas Count (which would follow the guidelines for deployed and stationed/assigned military personnel that are described in section C.1.a of this document).

2. Crews of U.S. Flag Maritime/Merchant Vessels

For the 2010 Census, crews of U.S. flag maritime/merchant vessels were counted based on where the vessel was located on Census Day. If the vessel was docked in a U.S. port or sailing from one U.S. port to another U.S. port, then the crewmembers were counted at their onshore usual residence in the United States. (Or if they had no onshore usual residence, they were counted at the vessel's U.S. port of departure.) Otherwise, the crewmembers were not counted in the census if the vessel was sailing from a U.S. port to a foreign port, sailing from a foreign port to a U.S. port, sailing from one foreign port to another foreign port, or docked in a foreign port.

For the 2020 Census, there would be no change to how the Census Bureau counts crews of U.S. flag maritime/merchant vessels that are docked in a U.S. port, sailing from one U.S. port to another U.S. port, sailing from one foreign port to another foreign port, or docked in foreign port. However, there would be a change for crews of U.S. flag maritime/merchant vessels that are sailing from a U.S. port to a foreign port or sailing from a foreign port to a U.S. port, such that the crewmembers of these vessels would be counted at their onshore usual residence in the United States. (Or if they have no onshore usual residence, they would be counted at the U.S. port that the vessel is sailing to or from.) This change seeks to count crews of U.S. flag maritime/merchant vessels in a way that is more consistent with the concept of usual residence, based on the fact that mariners sailing between U.S. and foreign ports typically have the same pattern of usual residence as mariners sailing between two U.S. ports (*i.e.,* they retain an onshore residence in the United States where they live and sleep most of the time).

3. Residential Treatment Centers for Juveniles

For the 2010 Census, all juveniles staying in residential treatment centers for juveniles on Census Day were counted at the facility. For the 2020 Census, juveniles staying in this type of facility would be counted at a usual home elsewhere if they have one (where they live and sleep most of the time around Census Day) and they report a useable address for that usual home elsewhere. If they do not have a usual home elsewhere, then they would be counted at the facility. This change seeks to count juveniles staying in residential treatment centers for juveniles in a way that is more consistent with the concept of usual residence, based on the short average length of stay at this facility type, and the fact that juveniles often retain a usual home elsewhere while staying at this facility type. More details about the considerations for this change can be found in section B of this document.

4. Religious Group Quarters

For the 2010 Census, people staying in religious group quarters were counted at a usual home elsewhere if they had one (where they lived and slept most of the time around Census Day) and they reported a useable address for that usual home elsewhere. If they did not have a usual home elsewhere, then they were counted at the facility. For the 2020 Census, all people staying in religious group quarters on Census Day would be counted at the facility.

D. The Proposed "2020 Census Residence Rule and Residence Situations"

The Residence Rule is used to determine where people are counted during the 2020 Census. The Rule says:

- Count people at their usual residence, which is the place where they live and sleep most of the time.
- People in certain types of group facilities on Census Day are counted at the group facility.
- People who do not have a usual residence, or who cannot determine a usual residence, are counted where they are on Census Day.

The following sections describe how the Residence Rule applies to certain living situations for which people commonly request clarification.

1. PEOPLE AWAY FROM THEIR USUAL RESIDENCE ON CENSUS DAY

(a) ***People away from their usual residence on Census Day, such as on a vacation or a business trip, visiting, traveling outside the U.S., or working elsewhere without a usual residence there (for example, as a truck driver or traveling salesperson)***—Counted at the residence where they live and sleep most of the time.

2. VISITORS ON CENSUS DAY

(a) ***Visitors on Census Day***—Counted at the residence where they live and sleep most of the time. If they do not have a usual residence to return to, they are counted where they are staying on Census Day.

3. FOREIGN CITIZENS IN THE U.S.

(a) ***Citizens of foreign countries living in the U.S.***—Counted at the U.S. residence where they live and sleep most of the time.

(b) ***Citizens of foreign countries living in the U.S. who are members of the diplomatic community***—Counted at the embassy, consulate, United Nations' facility, or other residences where diplomats live.

(c) ***Citizens of foreign countries visiting the U.S., such as on a vacation or business trip***—Not counted in the census.

4. PEOPLE LIVING OUTSIDE THE U.S.

(a) ***People deployed outside the U.S.***[6] ***on Census Day (while stationed or assigned in the U.S.) who are military or civilian employees of the U.S. Government***—Counted at the U.S. residence where they live and sleep most of the time, using administrative data provided by federal agencies.[7]

(b) ***People stationed or assigned outside the U.S. on Census Day who are military or civilian employees of the U.S. Government, as well as their dependents living with them outside the U.S.***—Counted as part of the U.S. federally affiliated overseas population, using administrative data provided by federal agencies.

(c) ***People living outside the U.S. on Census Day who are not military or civilian employees of the U.S. Government and are not dependents living with military or civilian employees of the U.S. Government***—Not counted in the stateside census.

5. PEOPLE WHO LIVE OR STAY IN MORE THAN ONE PLACE

(a) ***People living away most of the time while working, such as people who live at a residence close to where they work and return regularly to another residence***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(b) ***People who live or stay at two or more residences (during the week, month, or year), such as people who travel seasonally between residences (for example, snowbirds)***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(c) ***Children in shared custody or other arrangements who live at more than one residence***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

6. PEOPLE MOVING INTO OR OUT OF A RESIDENCE AROUND CENSUS DAY

(a) ***People who move into a new residence on or before Census Day***—Counted at the new residence where they are living on Census Day.

(b) ***People who move out of a residence on Census Day and do not move into a new residence until after Census Day***—Counted at the old residence where they were living on Census Day.

(c) ***People who move out of a residence before Census Day and do not move into a new residence until after Census Day***—Counted at the residence where they are staying on Census Day.

7. PEOPLE WHO ARE BORN OR WHO DIE AROUND CENSUS DAY

(a) ***Babies born on or before Census Day***—Counted at the residence where they will live and sleep most of the time, even if they are still in a hospital on Census Day.

(b) ***Babies born after Census Day***—Not counted in the census.

(c) ***People who die before Census Day***—Not counted in the census.

(d) ***People who die on or after Census Day***—Counted at the residence where they were living and sleeping most of the time as of Census Day.

8. RELATIVES AND NONRELATIVES

(a) ***Babies and children of all ages, including biological, step, and adopted children, as well as grandchildren***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day. (Only count babies born on or before Census Day.)

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[6] In this document, "Outside the U.S." and "foreign port" are defined as being anywhere outside the geographical area of the 50 United States and the District of Columbia. Therefore, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, the Pacific Island Areas (American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands), and all foreign countries are considered to be "outside the U.S." Conversely, "stateside," "U.S. homeport," and "U.S. port" are defined as being anywhere in the 50 United States and the District of Columbia.

[7] Military and civilian employees of the U.S. Government who are deployed or stationed/assigned outside the U.S. (and their dependents living with them outside the U.S.) are counted using administrative data provided by the Department of Defense and the other Federal agencies that employ them. If they are deployed outside the U.S. (while stationed/assigned in the U.S.), the administrative data are used to count them at their usual residence in the U.S. Otherwise, if they are stationed/assigned outside the U.S., the administrative data are used to count them (and their dependents living with them outside the U.S.) in their home state for apportionment purposes only.

(b) ***Foster children***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(c) ***Spouses and close relatives, such as parents or siblings***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(d) ***Extended relatives, such as grandparents, nieces/nephews, aunts/uncles, cousins, or in-laws***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(e) ***Unmarried partners***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(f) ***Housemates or roommates***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(g) ***Roomers or boarders***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(h) ***Live-in employees, such as caregivers or domestic workers***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

(i) ***Other nonrelatives, such as friends***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

9. PEOPLE IN RESIDENTIAL SCHOOL–RELATED FACILITIES

(a) ***Boarding school students living away from their parents' or guardians' home while attending boarding school below the college level, including Bureau of Indian Affairs boarding schools***—Counted at their parents' or guardians' home.

(b) ***Students in residential schools for people with disabilities on Census Day***—Counted at the school.

(c) ***Staff members living at boarding schools or residential schools for people with disabilities on Census Day***—Counted at the residence where they live and sleep most of the time. If they do not have a usual home elsewhere, they are counted at the school.

10. COLLEGE STUDENTS (and Staff Living in College Housing)

(a) ***College students living at their parents' or guardians' home while attending college in the U.S.***—Counted at their parents' or guardians' home.

(b) ***College students living away from their parents' or guardians' home while attending college in the U.S. (living either on-campus or off-campus)***—Counted at the on-campus or off-campus residence where they live and sleep most of the time. If they are living in college/university student housing (such as dormitories or residence halls) on Census Day, they are counted at the college/university student housing.

(c) ***College students living away from their parents' or guardians' home while attending college in the U.S. (living either on-campus or off-campus) but staying at their parents' or guardians' home while on break or vacation***—Counted at the on-campus or off-campus residence where they live and sleep most of the time. If they are living in college/university student housing (such as dormitories or residence halls) on Census Day, they are counted at the college/university student housing.

(d) ***College students who are U.S. citizens living outside the U.S. while attending college outside the U.S.***—Not counted in the stateside census.

(e) ***College students who are foreign citizens living in the U.S. while attending college in the U.S. (living either on-campus or off-campus)***—Counted at the on-campus or off-campus U.S. residence where they live and sleep most of the time. If they are living in college/university student housing (such as dormitories or residence halls) on Census Day, they are counted at the college/university student housing.

(f) ***Staff members living in college/university student housing (such as dormitories or residence halls) on Census Day***—Counted at the residence where they live and sleep most of the time. If they do not have a usual home elsewhere, they are counted at the college/university student housing.

11. PEOPLE IN HEALTH CARE FACILITIES

(a) ***People in general or Veterans Affairs hospitals (except psychiatric units) on Census Day, including newborn babies still in the hospital on Census Day***—Counted at the residence where they live and sleep most of the time. Newborn babies are counted at the residence where they will live and sleep most of the time. If patients or staff members do not have a usual home elsewhere, they are counted at the hospital.

(b) ***People in mental (psychiatric) hospitals and psychiatric units in other hospitals (where the primary function is for long-term non-acute care) on Census Day***—Patients are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(c) ***People in assisted living facilities***[8] ***where care is provided for individuals who need help with the activities of daily living but do not need the skilled medical care that is provided in a nursing home***—Residents and staff members are counted at the residence where they live and sleep most of the time.

(d) ***People in nursing facilities/skilled-nursing facilities (which provide long-term non-acute care) on Census Day***—Patients are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(e) ***People staying at in-patient hospice facilities on Census Day***—Counted at the residence where they live and sleep most of the time. If patients or staff members do not have a usual home elsewhere, they are counted at the facility.

12. PEOPLE IN HOUSING FOR OLDER ADULTS

(a) ***People in housing intended for older adults, such as active adult communities, independent living, senior apartments, or retirement***

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[8] Nursing facilities/skilled-nursing facilities, in-patient hospice facilities, assisted living facilities, and housing intended for older adults may coexist within the same entity or organization in some cases. For example, an assisted living facility may have a skilled-nursing floor or wing that meets the nursing facility criteria, which means that specific floor or wing is counted according to the guidelines for nursing facilities/skilled-nursing facilities, while the rest of the living quarters in that facility are counted according to the guidelines for assisted living facilities.

communities—Residents and staff members are counted at the residence where they live and sleep most of the time.

13. U.S. MILITARY PERSONNEL

(a) ***U.S. military personnel assigned to military barracks/dormitories in the U.S. on Census Day***—Counted at the military barracks/dormitories.

(b) ***U.S. military personnel (and dependents living with them) living in the U.S. (living either on base or off base) who are not assigned to barracks/dormitories on Census Day***—Counted at the residence where they live and sleep most of the time.

(c) ***U.S. military personnel assigned to U.S. military vessels with a U.S. homeport on Census Day***—Counted at the onshore U.S. residence where they live and sleep most of the time. If they have no onshore U.S. residence, they are counted at their vessel's homeport.

(d) ***People who are active duty patients assigned to a military treatment facility in the U.S. on Census Day***—Patients are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(e) ***People in military disciplinary barracks and jails in the U.S. on Census Day***—Prisoners are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(f) ***U.S. military personnel who are deployed outside the U.S. (while stationed in the U.S.) and are living on or off a military installation outside the U.S. on Census Day***—Counted at the U.S. residence where they live and sleep most of the time, using administrative data provided by the Department of Defense.

(g) ***U.S. military personnel who are stationed outside the U.S. and are living on or off a military installation outside the U.S. on Census Day, as well as their dependents living with them outside the U.S.***—Counted as part of the U.S. federally affiliated overseas population, using administrative data provided by the Department of Defense.

(h) ***U.S. military personnel assigned to U.S. military vessels with a homeport outside the U.S. on Census Day***—Counted as part of the U.S. federally affiliated overseas population, using administrative data provided by the Department of Defense.

14. MERCHANT MARINE PERSONNEL ON U.S. FLAG MARITIME/MERCHANT VESSELS

(a) ***Crews of U.S. flag maritime/merchant vessels docked in a U.S. port, sailing from one U.S. port to another U.S. port, sailing from a U.S. port to a foreign port, or sailing from a foreign port to a U.S. port on Census Day***—Counted at the onshore U.S. residence where they live and sleep most of the time. If they have no onshore U.S. residence, they are counted at their vessel. If the vessel is docked in a U.S. port, sailing from a U.S. port to a foreign port, or sailing from a foreign port to a U.S. port, crewmembers with no onshore U.S. residence are counted at the U.S. port. If the vessel is sailing from one U.S. port to another U.S. port, crewmembers with no onshore U.S. residence are counted at the port of departure.

(b) ***Crews of U.S. flag maritime/merchant vessels engaged in U.S. inland waterway transportation on Census Day***—Counted at the onshore U.S. residence where they live and sleep most of the time.

(c) ***Crews of U.S. flag maritime/merchant vessels docked in a foreign port or sailing from one foreign port to another foreign port on Census Day***—Not counted in the stateside census.

15. PEOPLE IN CORRECTIONAL FACILITIES FOR ADULTS

(a) ***People in federal and state prisons on Census Day***—Prisoners are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(b) ***People in local jails and other municipal confinement facilities on Census Day***—Prisoners are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(c) ***People in federal detention centers on Census Day, such as Metropolitan Correctional Centers, Metropolitan Detention Centers, Bureau of Indian Affairs Detention Centers, Immigration and Customs Enforcement (ICE) Service Processing Centers, and ICE contract detention facilities***—Prisoners are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(d) ***People in correctional residential facilities on Census Day, such as halfway houses, restitution centers, and prerelease, work release, and study centers***—Residents are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

16. PEOPLE IN GROUP HOMES AND RESIDENTIAL TREATMENT CENTERS FOR ADULTS

(a) ***People in group homes intended for adults (non-correctional) on Census Day***—Residents are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(b) ***People in residential treatment centers for adults (non-correctional) on Census Day***—Counted at the residence where they live and sleep most of the time. If residents or staff members do not have a usual home elsewhere, they are counted at the facility.

17. PEOPLE IN JUVENILE FACILITIES

(a) ***People in correctional facilities intended for juveniles on Census Day***—Juvenile residents are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(b) ***People in group homes for juveniles (non-correctional) on Census Day***—Juvenile residents are counted at the facility. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the facility.

(c) ***People in residential treatment centers for juveniles (non-correctional) on Census Day***—Counted at the residence where they live and sleep most of the time. If juvenile residents or staff members do not have a usual home elsewhere, they are counted at the facility.

18. PEOPLE IN TRANSITORY LOCATIONS

(a) ***People at transitory locations such as recreational vehicle (RV) parks, campgrounds, hotels and motels (including those on military sites), hostels, marinas, racetracks, circuses, or carnivals***—Anyone, including staff members, staying at the transitory location are counted at the residence where they live and sleep most of the time. If they do not have a usual home elsewhere, or they cannot determine a place where they live most of the time, they are counted at the transitory location.

19. PEOPLE IN WORKERS' RESIDENTIAL FACILITIES

(a) ***People in workers' group living quarters and Job Corps Centers on Census Day***—Counted at the residence where they live and sleep most of the time. If residents or staff members do not have a usual home elsewhere, they are counted at the facility.

20. PEOPLE IN RELIGIOUS-RELATED RESIDENTIAL FACILITIES

(a) ***People in religious group quarters, such as convents and monasteries, on Census Day***—Counted at the facility.

21. PEOPLE IN SHELTERS AND PEOPLE EXPERIENCING HOMELESSNESS

(a) ***People in domestic violence shelters on Census Day***—People staying at the shelter (who are not staff) are counted at the shelter. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the shelter.

(b) ***People who, on Census Day, are in temporary group living quarters established for victims of natural disasters***—Anyone, including staff members, staying at the facility are counted at the residence where they live and sleep most of the time. If they do not have a usual home elsewhere, they are counted at the facility.

(c) ***People who, on Census Day, are in emergency and transitional shelters with sleeping facilities for people experiencing homelessness***—People staying at the shelter (who are not staff) are counted at the shelter. Staff members are counted at the residence where they live and sleep most of the time. If staff members do not have a usual home elsewhere, they are counted at the shelter.

(d) ***People who, on Census Day, are at soup kitchens and regularly scheduled mobile food vans that provide food to people experiencing homelessness***—Counted at the residence where they live and sleep most of the time. If they do not have a usual home elsewhere, they are counted at the soup kitchen or mobile food van location where they are on Census Day.

(e) ***People who, on Census Day, are at targeted non-sheltered outdoor locations where people experiencing homelessness stay without paying***—Counted at the outdoor location where they are on Census Day.

(f) ***People who, on Census Day, are temporarily displaced or experiencing homelessness and are staying in a residence for a short or indefinite period of time***—Counted at the residence where they live and sleep most of the time. If they cannot determine a place where they live most of the time, they are counted where they are staying on Census Day.

Dated: June 23, 2016.

John H. Thompson,

Director, Bureau of the Census.

[FR Doc. 2016–15372 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA–2016–F–1805]

Society of the Plastics Industry, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Keller and Heckman LLP on behalf of the Society of the Plastics Industry, Inc. (Petitioner or SPI), requesting that we amend our food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned.

DATES: The food additive petition was filed on May 11, 2016. Submit either electronic or written comments by August 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–F–1805 for "Filing of Food Additive Petition: Society of the Plastics Industry, Inc." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas C. Zebovitz, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1244.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 6B4816) submitted on behalf of the Society of the Plastics Industry, Inc. (Petitioner or SPI) by Keller and Heckman LLP, 1001 G Street NW., Suite 500 West, Washington, DC 20001. The petition proposes that we amend 21 CFR 177.1210 to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because the use has been intentionally and permanently abandoned.

II. Abandonment

Under section 409(i) of the FD&C Act, we "shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." Our regulations specific to administrative actions for food additives provide that the Commissioner, on his own initiative or on the petition of any interested person, under 21 CFR part 10, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive (21 CFR 171.130(a)). These regulations further provide that any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions (21 CFR 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that regulatory authorization is no longer necessary because the use of the food additive has been abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (*e.g.,* if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (*e.g.,* if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The SPI petition includes the following information to support the claim that the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers has been abandoned in the U.S. market. The petition states that three of the four companies that filed the food additive petitions that resulted in the listing for potassium perchlorate in 21 CFR 177.1210 are still operating, and that the fourth company is no longer in business. The Petitioner polled the three companies about their use of potassium perchlorate in closure-sealing gaskets for food containers asking them to verify that they do not: (1) Currently manufacture potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States; (2) currently import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States; (3) intend to manufacture or import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States in the future; or (4) currently maintain any inventory of potassium perchlorate for sale or distribution into commerce that is intended to be marketed for use as a component of closures with sealing gaskets for food containers in the United States. The petition includes signed letters from the three companies confirming agreement to these four points.

The petition also includes a signed letter from American Pacific Corporation, Western Electrochemical Company (AMPAC), which the Petitioner states is the sole domestic manufacturer of potassium perchlorate in the United States. The letter states that AMPAC does not manufacture, import, or maintain any inventory of potassium perchlorate for sale or distribution into commerce into the food-contact market for use in closure-sealing gaskets for food containers in the United States.

The petition also asserts that SPI surveyed the member companies that make up SPI's Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC). According to the petition, no FDCPMC member company responded that it had any knowledge or reason to believe that potassium perchlorate was being manufactured, used, distributed, or imported into the United States for use in the manufacture of closures with sealing gaskets for food-contact applications. The petition also states that SPI has been unable to identify any company with records indicating that potassium perchlorate was actually used as a component of closure-sealing gaskets for food containers.

A supplement to the petition, dated May 16, 2016, asserts that SPI contacted all known U.S.-based manufacturers of gaskets for food-contact applications, which the Petitioner asserts constitute the substantial majority, if not all of such manufacturers. The supplement asserts that each company indicated to SPI that it does not continue to use potassium perchlorate in the manufacture of gaskets for food-contact materials.

We expressly request comments on the Petitioner's request to amend 21 CFR 177.1210 of the food additive regulations to no longer permit the use of potassium perchlorate in closure-sealing gaskets used for food containers. As noted, the basis for the proposed amendment is that the use of potassium perchlorate in closure-sealing gaskets for food containers has been permanently and completely abandoned. Accordingly, we request comments that address whether this use of potassium perchlorate has been completely abandoned, such as information on whether closure-sealing gaskets containing potassium perchlorate are currently being introduced or delivered for introduction into the U.S. market. We are not aware of information that suggests continued use of potassium perchlorate as a component of closure-sealing gaskets in contact with food.

We are providing the public with 60 days to submit comments. We anticipate that some interested persons may wish to provide FDA with certain information they consider to be trade secret or confidential commercial information (CCI) that would be exempt under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to FDA as CCI or trade secret by clearly marking both the document and the specific information as "confidential." Information so marked will not be disclosed except in accordance with the Freedom of Information Act (5 U.S.C. 552) and our disclosure regulations (21 CFR part 20). For electronic submissions to *http://www.regulations.gov,* indicate in the "comments" box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of the use of potassium perchlorate in closure-sealing gaskets for food containers because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing the safety of potassium perchlorate or containing safety information on this substance in our evaluation of this petition. In addition to our consideration of this petition, we are considering information on the safety of potassium perchlorate as an additive in closure-sealing gaskets for food containers as part of our consideration of a petition designated for reference as FAP 4B4808 (see 80 FR 13508 (March 16, 2015)). We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 24, 2016.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–15474 Filed 6–29–16; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2014–0221; FRL–9948–56–Region 6]

Approval and Promulgation of Implementation Plans; Oklahoma; Revisions to Major New Source Review Permitting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve severable portions of revisions to the Oklahoma New Source Review (NSR) State Implementation Plan (SIP) submitted by the State of Oklahoma on June 24, 2010; July 16, 2010; December 27, 2010; February 6, 2012; and January 18, 2013. These revisions update the Prevention of Significant Deterioration (PSD) and Nonattainment NSR (NNSR) permit programs to be consistent with federal permitting requirements and make general updates to the Oklahoma SIP to support major NSR permitting. We are proposing this action under section 110, parts C and D of the Clean Air Act (CAA).

DATES: Written comments must be received on or before August 1, 2016.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2014–0221, at *http://www.regulations.gov* or via email to *wiley.adina@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact Ms. Adina Wiley, (214) 665–2115, *wiley.adina@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Adina Wiley, (214) 665–2115, *wiley.adina@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Adina Wiley or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we," "us," or "our" is used, we mean the EPA.

I. Background

A. The CAA and SIPs

The CAA at Section 110(a)(2)(C) requires states to develop and submit to the EPA for approval into the SIP, preconstruction review and permitting programs applicable to certain new and modified stationary sources of air pollutants for attainment/unclassifiable and nonattainment areas that cover both major and minor new sources and modifications, collectively referred to as the NSR SIP. The CAA NSR SIP program is composed of three separate programs: PSD, NNSR, and Minor NSR. PSD is established in part C of title I of the CAA and applies in areas that are designated as meeting the National Ambient Air Quality Standards (NAAQS), *i.e.,* "attainment areas," as well as areas designated as "unclassifiable" because there is insufficient information to determine if the area meets the NAAQS. The NNSR SIP program is established in part D of title I of the CAA and applies in areas that are designated as not being in attainment of the NAAQS, *i.e.*, "nonattainment areas." The Minor NSR SIP program addresses construction or modification activities that do not emit, or have the potential to emit, beyond certain major source/major modification thresholds and thus do not qualify as "major" and applies regardless of the designation of the area in which a source is located. Any submitted SIP revision must meet the applicable requirements for SIP elements in section 110 of the Act, and be consistent with all applicable statutory and regulatory requirements. The EPA regulations governing the criteria that states must satisfy for EPA approval of the NSR programs as part of the SIP are contained in 40 CFR Sections 51.160–51.166. Regulations specific to NNSR are contained in 40 CFR 51.165; PSD specific regulations are found in 40 CFR 51.166. The State of Oklahoma submitted revisions to the Oklahoma SIP related to its title I Major NSR permitting programs—PSD and NNSR. In addition to the specific revisions for Major NSR permitting, the State of Oklahoma also submitted revisions to the General Oklahoma SIP requirements that support major NSR permitting activities.

B. Overview of the Revisions to the General Provisions of the Oklahoma SIP

On July 16, 2010, the State of Oklahoma submitted revisions to the General Provisions in the Oklahoma SIP that had been adopted by the State and became effective from 2003–2012. Revisions submitted to the EPA for review included updates to the definitions and units, abbreviations, and acronyms used throughout the Oklahoma SIP; provisions establishing the ability to incorporate by reference federal requirements; revisions to the PSD increments regulated under the Oklahoma SIP; and updates to the Emission Inventory provisions.

C. Overview of the Revisions to the Oklahoma Major Source Permitting Programs

The State of Oklahoma submitted revisions to the Oklahoma PSD and NNSR Programs on June 24, 2010; July 16, 2010; February 6, 2012; and January 18, 2013. The revisions to the Oklahoma PSD and NNSR programs under review in this action have been submitted to address amendments that the EPA has made to the federal PSD and NNSR regulations as contained in the following final rules:

- NSR Reform Rule (67 FR 800186, December 31, 2002) and (68 FR 63021, November 7, 2003);
- Implementation of the 8-hour Ozone (O_3) NAAQS-Phase 2; Final Rule to Implement Certain Aspects of the 1990 Amendments Relating to NSR and PSD as They Apply to Carbon Monoxide (CO), PM and O_3 NAAQS (70 FR 71612, November 29, 2005);
- PSD and NNSR: Reasonable Possibility in Recordkeeping (72 FR 72607, December 21, 2007);
- NSR $PM_{2.5}$ Implementation Rule (73 FR 28321, May 16, 2008);
- PSD for $PM_{2.5}$—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC) (75 FR 64864, October 20, 2010);
- GHG Tailoring Rule (75 FR 31514, June 3, 2010) (specific to PSD permitting only);
- PSD and NNSR: Reconsideration of Inclusion of Fugitive Rule (76 FR 17548, March 30, 2011).

D. Revisions Not Covered in This Proposed Action

Some severable provisions submitted by the State of Oklahoma on June 24, 2010; July 16, 2010; February 6, 2012; and January 18, 2013 are not addressed in today's action. In some instances, the EPA has taken separate actions to propose or finalize a decision on these severable provisions. For the remaining provisions, the EPA has severed the submitted provisions from today's rulemaking and will address them at a later date. The Technical Support Document accompanying our rulemaking identifies the provisions that we are not evaluating or proposing in this action.

II. The EPA's Evaluation

A. Evaluation of the Revisions to the General Provisions of the Oklahoma SIP

We have evaluated revisions to the General Provisions for the Oklahoma SIP submitted July 16, 2010; December 27, 2010; February 6, 2012; and January 18, 2013. These revisions, if approved by the EPA, would update the Oklahoma SIP to be consistent with current Oklahoma regulations and support the PSD and NNSR permitting programs in Oklahoma. We find that all of the revisions summarized below are consistent with federal requirements for SIP development under 40 CFR part 51; accordingly, we propose to approve the submitted rules as part of the Oklahoma SIP.

- The revisions to OAC 252:100–1–1, Purpose, and OAC 252:100–1–2, Definitions, effective June 12, 2003 and submitted on July 16, 2010, update the terms, phrases, and statutory definitions used throughout the Oklahoma SIP.
- The revisions to the General Definitions at OAC 252:100–1–3 effective on June 12, 2003; July 1, 2008; July 1, 2009; June 15, 2006; July 1, 2011; and July 1, 2012.[1] These revisions provide updates to maintain consistency with federal definitions in 40 CFR part 51 and remove obsolete or duplicative definitions.
- New provisions at OAC 252:100–1–4 effective on June 12, 2003; July 1, 2009; and July 1, 2011 that establish the units, abbreviations, and acronyms germane to the Oklahoma SIP.
- New provisions at OAC 252:100–2–1, 252:100–2–3, and Appendix Q effective July 1, 2012, to provide the authority to incorporate by reference (IBR) federal requirements and to specifically identify the requirements that are incorporated into the Oklahoma regulations and SIP. The EPA is only proposing to approve the IBR of the identified portions of 40 CFR parts 50 and 51. All remaining portions of Appendix Q as submitted July 16, 2010 and January 18, 2013, were returned to the ODEQ by letters dated March 4, 2016 and May 16, 2016, respectively.
- Revisions to OAC 252:100–3–4 effective June 15, 2005 and July 1, 2011, to maintain consistency with federal requirements and adopt and implement the PSD $PM_{2.5}$ increments promulgated by the EPA on October 20, 2010.
- New OAC 252:100, Appendix P—Regulated Air Pollutants, effective June 15, 2007, to identify the pollutants regulated under the CAA and EPA regulations.
- Revisions to the regulations at OAC 252:100, Subchapter 5—Registration, Emission Inventory, and Annual Operating Fees on July 16, 2010. These amendments, update the Subchapter 5 Definitions at OAC 252:100–5–1.1 to remove obsolete definitions and promote clarity and revise the Emission Inventory provisions at OAC 252:100–5–1.2 to include non-substantive edits to promote clarity to state Emission Inventory practices.[2]

B. Evaluation of the Revisions to the Oklahoma Major NSR Permitting Programs

We evaluated amendments to the Oklahoma PSD and NNSR programs submitted on June 24, 2010; July 16, 2010, February 6, 2012, and January 18, 2013. These submitted revisions update the general requirements for Oklahoma Major NSR Permitting Programs, and provide specific updates to the Oklahoma PSD and NNSR Permitting Programs at OAC 252:100–8–1.1, 8–30, 8–31, 8–32, 8–32.1, 8–32.2, 8–32.2, 8–33, 8–34, 8–35, 8–35.1, 8–35.2, 8–36, 8–36.2, 8–37, 8–38, 8–39, 8–50, 8–50.1, 8–51, 8–51.1, 8–52, 8–53, 8–54, 8–54.1, 8–55, 8–56, and 8–57.[3] These amendments, if approved by the EPA, would update the PSD and NNSR programs to be consistent with federal permitting requirements and provide clarity to the existing SIP-approved rules. The EPA's evaluation of the Oklahoma SIP submittals includes an analysis of how the Oklahoma regulations comport with the federal permitting requirements. We find that in most cases, the state regulatory language is identical to that of the federal rule. Where the regulatory language is not identical, we find it is consistent with the intent of the federal rules and definitions. The EPA is therefore proposing to approve the submitted rules as part of the Oklahoma PSD and NNSR SIP.

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[1] On January 18, 2013, Oklahoma submitted a revision to the definition of "carbon dioxide equivalent" at OAC 252:100–1–3, effective July 1, 2012. The EPA separately proposed disapproval of this provision on January 11, 2016. *See* 81 FR 1141.

[2] The revision to OAC 252:100–5–2.1(a)(3) effective June 11, 2014 and submitted July 16, 2010, was withdrawn by the Oklahoma Secretary of Energy and Environment on January 28, 2015. As such, this provision is no longer before us for review.

1. NSR Reform Rule

The EPA promulgated its NSR Reform Program rules on December 31, 2002 (67 FR 80186). On November 7, 2003 (68 FR 63021), the EPA promulgated a final action on its reconsideration of the December 31, 2002, NSR Reform Program rules. Our evaluation of the Oklahoma SIP submittals demonstrates the ODEQ has adopted and submitted revisions to the PSD and NNSR permitting programs that are sufficient for the ODEQ to implement the required elements of NSR Reform.

The rule revisions effective June 15, 2006, submitted as a revision to the Oklahoma SIP on July 16, 2010, include revisions to OAC 252:100 Part 7—Prevention of Significant (PSD) Requirements for Attainment Areas. The submission covers Applicability, PSD requirements, Actuals PALs, and Definitions that implement the NSR Reform revisions to PSD. To be approvable under the SIP, states implementing Part C (PSD permit program in 40 CFR 51.166) must include the EPA's December 31, 2002, changes as minimum PSD program elements. The following summary demonstrates the revisions to the Oklahoma PSD program satisfy the federal PSD program requirements:

- Incorporation of a new method for determining baseline actual emissions; defined in OAC 252:100–8–30 and OAC 252:100–8–31;
- Incorporation of the actual-to-projected-actual methodology for determining whether a major modification has occurred; found in OAC 252:100–8–30; and
- Inclusion of rules that allow major stationary sources to comply with Plantwide Applicability Limits (PALs) to avoid having a significant emissions increase that triggers the requirements of the major NSR program; found OAC 252:100–8–38.

The rule revisions effective June 15, 2006, submitted as a revision to the Oklahoma SIP on July 16, 2010, also include revisions to OAC 252:100 Part 9—Major Sources Affecting Nonattainment Areas. The submission covers Applicability, NNSR requirements, Actuals PALs, and Definitions that implement the NSR Reform revisions to NNSR. To be approvable under the SIP, states implementing Part D (NNSR permit program in 40 CFR 51.165) must include the EPA's December 31, 2002, changes as minimum NNSR program elements. The following summary demonstrates that the revisions to the Oklahoma NNSR program satisfy the federal NNSR program requirements.

- Incorporation of a new method for determining baseline actual emissions; defined in OAC 252:100–8–50 and OAC 252:100–8–51;
- Incorporation of the actual-to-projected-actual methodology for determining whether a major modification has occurred; found in OAC 252:100–8–50; and
- Inclusion of rules that allow major stationary sources to comply with Plantwide Applicability Limits (PALs) to avoid having a significant emissions increase that triggers the requirements of the major NSR program; found OAC 252:100–8–56.

2. Final Rule To Implement the 8-Hour Ozone (O_3) NAAQS—Phase 2 and Certain Aspects of the 1990 Amendments Relating to NSR and PSD as They Apply to Carbon Monoxide (CO), PM and O_3 NAAQS (O_3 NAAQS Implementation Rule)

The EPA finalized the O_3 NAAQS Implementation Rule to provide additional regulatory requirements under the PSD and NNSR SIP programs regarding the implementation of the 8-hour ozone NAAQS. *See* 70 FR 71612, November 29, 2005. Regarding NSR, this rule is based on the proposed rule published on June 2, 2003 to implement the 8-hour O_3 NAAQS, as well as the proposed rule published on July 23, 1996 for PSD and NNSR. *See* 68 FR 32802 and 61 FR 38305, respectively. These changes provide a consistent national program for permitting major stationary sources under section 110(a)(2)(C) and parts C and D of title I of the CAA, including major stationary sources of any ozone precursor in ozone nonattainment areas.

The revisions to the Oklahoma PSD Program address the required elements of the EPA's final 8-hour ozone NAAQS Phase 2 rule as follows:

- The Oklahoma PSD program contains a revised definition of "major stationary source" at OAC 252:100–8–31, which specifies that a major source that is major for VOC or NO_X is considered major for ozone.
- The Oklahoma PSD program contains a revised definition of "major modification" at OAC 252:100–8–31, which specifies that any significant increase or net emissions increase at a major stationary source that is significant for VOC or NO_X shall be considered significant for ozone.
- The Oklahoma PSD program contains a revised definition of "significant" at OAC 252:100–8–31, which specifies that the SER for ozone is 40 TPY of VOC or NO_X.
- The Oklahoma PSD program contains a revised definition of "regulated NSR pollutant" at OAC 252:100–8–31, which specifies that VOC and NO_X are precursors to ozone and thus regulated pollutants.
- The Oklahoma PSD program contains a revised exemption from PSD monitoring at OAC 252:100–8–33(c)(1)(F), which specifies that no de minimis air quality level is provided for ozone.

The EPA's final 8-hour ozone NAAQS Phase 2 Rule also codified requirements added to part D of Title I of the CAA in the 1990 Amendments related to permitting of major stationary sources in areas that are nonattainment for the O_3, PM, and CO NAAQS. Second, the EPA revised the criteria for crediting emissions reductions credits from shutdowns and curtailments as offsets. Third, revisions to the regulations for permitting of major stationary sources in nonattainment areas in interim periods between designation of new nonattainment areas and the EPA's approval of a revised SIP. Fourth, the EPA changed the regulations that impose a ban prohibiting construction of new or modified major stationary sources in nonattainment area where the State fails to have an implementation plan meeting all of the requirements of part D. The revisions to the Oklahoma NNSR Program address the required elements of the EPA's final 8-hour Ozone NAAQS Phase 2 rule as follows:

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[3] As identified in the TSD, the EPA is taking no action at this time on the submitted revisions to OAC 252:100–8–2, 8–4, 8–5, 8–6, 8–6.1, 8–6.3, 8–7, 8–7.2, 8–8, and 8–36.1.

- The Oklahoma NNSR program at OAC 252:100–8–51 incorporates by reference the federal NNSR definition of "major stationary source" at 40 CFR 51.165(a)(1)(iv) as of July 1, 2010.
- The definition of "major modification" at OAC 252:100–8–51 was revised by adding a new paragraph (C) and new OAC 252:100–8–54.1(a) together requiring NO_X to be regulated as an ozone precursor in an ozone nonattainment area consistent with the federal requirements at 40 CFR 51.165(a)(1)(v) and (a)(3)(8).
- The Oklahoma NNSR program at OAC 252:100–8–51 incorporates by reference the federal NNSR definition of "significant" at 40 CFR 51.165(a)(1)(x) as of July 1, 2010.
- New OAC 252:100–8–51.1(b) incorporates by reference the emission offset requirements in 40 CFR 51.165(a)(9) as of July 2, 2007.
- New OAC 252:100–8–54.1(b) makes the PM_{10} requirements apply to the PM_{10} precursors consistent with the requirements at 40 CFR 51.165(a)(10).

3. PSD and NNSR: Reasonable Possibility in Recordkeeping Rulemaking

The EPA finalized PSD and NNSR: Reasonable Possibility in Recordkeeping on December 21, 2007. *See* 72 FR 72607. This rule clarifies the "reasonable possibility" recordkeeping and reporting standards of our 2002 NSR Reform rules. The "reasonable possibility" standard identifies for sources and reviewing authorities the criteria under which an owner or operator of a major stationary source undergoing a physical change or change in the method of operation that does not trigger major NSR permitting requirements for a given regulated NSR pollutant must keep records. The standard also specifies when the recordkeeping and reporting requirements apply to such sources.

The Oklahoma PSD program does not include the reasonable possibility provisions as promulgated by EPA at 40 CFR 51.166(r)(6)(vi). Instead, in the Oklahoma PSD program, any source using the "projected actual emissions" methodology is required to comply with the recordkeeping requirements at 40 CFR 51.166(r)(6)(i)–(v). Similarly, the revisions to the Oklahoma NNSR program effective June 15, 2006, submitted July 16, 2010, incorporate by reference as of January 2, 2006, the requirements in 40 CFR 51.165(a)(6)(i) through (a)(6)(v), and do not include the reasonable possibility provisions promulgated at 40 CFR 51.165(a)(6)(vi).

The Oklahoma Department of Environmental Quality submitted a letter of interpretation on February 8, 2016, that explained how the Oklahoma PSD program applies the recordkeeping, monitoring and reporting requirements consistent with 40 CFR 51.166(r)(6)(i)–(v) to all sources that use the "projected actual emissions" methodology; not just a subset of sources for which there is a "reasonable possibility" that a project would result in a significant emissions increase of a regulated NSR pollutant. These requirements apply to *any* source using the "projected actual emissions" methodology. Therefore, the EPA believes that the Oklahoma SIP does not need to include the reasonable possibility provisions at 40 CFR 51.166(r)(6)(vi). This requirement for all sources to maintain records, monitor emissions and report in accordance with 40 CFR 51.166(r)(6)(i)–(v) is more stringent than federal requirements and is therefore approvable. While the February 8, 2016, letter is specific to the Oklahoma PSD program and the requirements at OAC 252:100–8–36.2, we find that the Oklahoma NNSR program is structured similarly and the same conclusion would apply. Any source using the "projected actual emissions" methodology is required to meet the recordkeeping and reporting requirements consistent with 40 CFR 51.165(a)(6)(i)–(v). Therefore, the Oklahoma SIP does not need to include the reasonable possibility provisions at 40 CFR 51.165(a)(6)(vi).

4. Revisions to the PSD and NNSR Programs for $PM_{2.5}$ Implementation

The EPA promulgated two rules establishing both required and optional implementation elements for PSD and NNSR permitting programs for $PM_{2.5}$: the May 16, 2008 final rule for Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$) (referred to as the NSR $PM_{2.5}$ Implementation Rule), 73 FR 28321; and the October 20, 2010 final rule for Prevention of Significant Deterioration (PSD) for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC) (referred to as the $PM_{2.5}$ PSD Increments—SILs—SMC Rule), 75 FR 64864. Both the NSR $PM_{2.5}$ Implementation Rule and the $PM_{2.5}$ PSD Increments—SILs—SMC Rule have also been the subject of litigation. Following is a discussion of how the Oklahoma PSD and NNSR programs satisfy the required elements of these two rulemakings and address the concerns raised in the subsequent litigation.

a. NSR $PM_{2.5}$ Implementation Rule

Our evaluation of the February 6, 2012, revisions to the Oklahoma PSD permitting program presented below and in our accompanying TSD, demonstrates that the Oklahoma PSD program includes all of the PSD required elements of the NSR $PM_{2.5}$ Implementation Rule.

- Regulation of Direct $PM_{2.5}$ and Precursors: The revised definition of "regulated NSR pollutant" at OAC 252:100–8–31 is consistent with the federal definition of "regulated NSR pollutant" at 40 CFR 51.166(b)(49) and identifies precursors to $PM_{2.5}$ in attainment areas. With respect to $PM_{2.5}$, the revised definition of "regulated pollutant" at OAC 252:100–8–31 identifies sulfur dioxide and nitrogen oxides as regulated $PM_{2.5}$ precursors while volatile organic compounds (VOCs) are not regulated $PM_{2.5}$ precursors in $PM_{2.5}$ attainment areas in Oklahoma.
- Establish SERs: The revisions to the PSD definition of "significant" at OAC 252:100–8–31 establishes significant emission rates for direct $PM_{2.5}$ and for NO_X and SO_2 and $PM_{2.5}$ precursors.
- Condensable $PM_{10}/PM_{2.5}$ Emissions: The revised definition of "regulated NSR pollutant" at OAC 252:100–8–31 is consistent with the federal requirements promulgated on May 16, 2008 at 40 CFR 51.166(b)(49)(vi). Note that the EPA subsequently promulgated a correction to the definition of "regulated NSR pollutant" with regard to the way in which condensable particulate matter is to be addressed with regard to emissions of PM at 40 CFR 51.166(b)(49)(i)(*a*). The correction clarified that permit applicants are not required to consider the condensable portion of particulate matter in applicability determinations and in establishing emission limitations concerning "PM emissions," a term that represents a size range or indicator of particulate matter not considered to be a criteria pollutant. *See* 77 FR 65107, October 25, 2012. Although the ODEQ revisions do not reflect this amendment of the federal condensable provision, the State's revision to the PSD program to address condensable emissions is nonetheless approvable as it is more stringent than the current federal requirements for regulating condensibles as modified by the EPA in the October 25, 2012 final rule.

Based on the analysis presented below and in our accompanying TSD, the EPA is also proposing to find that the February 6, 2012, revision to the Oklahoma NNSR permitting program includes all of the NNSR requirements of the NSR $PM_{2.5}$ Implementation Rule for the following reasons:

- Regulation of Direct $PM_{2.5}$ and Precursors: The revised definition of "regulated NSR pollutant" at OAC 252:100–8–51 is consistent with the federal definition of "regulated NSR pollutant" at 40 CFR 51.165(a)(1)(xxxvii) and identifies precursors to $PM_{2.5}$ in nonattainment areas. With respect to $PM_{2.5}$, the revised definition of "regulated pollutant" at OAC 252:100–8–51 identifies sulfur dioxide and nitrogen oxides as regulated $PM_{2.5}$ precursors while volatile organic compounds (VOCs) and ammonia are not regulated $PM_{2.5}$ precursors in $PM_{2.5}$ nonattainment areas in Oklahoma. We note there are currently no $PM_{2.5}$ nonattainment areas in Oklahoma.
- Establish SERs: The February 6, 2012, submittal incorporates by reference the definition of "significant" at 40 CFR 51.165(a)(1) as it exists on July 1, 2011, and will therefore include significant emission rates for direct $PM_{2.5}$ and for sulfur dioxide and nitrogen oxides as $PM_{2.5}$ precursors as promulgated by the EPA at 40 CFR 51.165(a)(1)(xxxvii)(C) and (D) on May 16, 2008.
- Condensable PM_{10}/$PM_{2.5}$ Emissions: The revised definition of "regulated NSR pollutant" at OAC 252:100–8–51 is consistent with the federal requirements promulgated on May 16, 2008 at 40 CFR 51.165(a)(1)(xxxvii).

b. The EPA's Analysis of the Revisions to the Oklahoma PSD and NNSR Permitting Program Submittal in Light of the Litigation on the May 16, 2008 NSR $PM_{2.5}$ Implementation Rule

On January 4, 2013, the U.S. Court of Appeals for the District of Columbia Circuit, in *Natural Resources Defense Council* v. *EPA*[4] issued a decision that remanded the EPA's 2007 and 2008 rules implementing the 1997 $PM_{2.5}$ NAAQS. With respect to the requirements for implementation of the $PM_{2.5}$ NAAQS in nonattainment areas, the Court found that the EPA erred in implementing the $PM_{2.5}$ NAAQS in these rules solely pursuant to the general implementation provisions of subpart 1 of part D of title I of the CAA, rather than pursuant to the additional implementation provisions specific to particulate matter nonattainment areas in subpart 4. The Court ordered the EPA to "repromulgate" these rules pursuant to subpart 4 consistent with this opinion." *Id.* at 437. Subpart 4 of Part D, Title I of the CAA establishes additional provisions for particulate matter nonattainment areas.

The 2008 $PM_{2.5}$ NSR Implementation Rule addressed by the *NRDC* decision promulgated NSR requirements for implementation of $PM_{2.5}$ in both nonattainment areas (NNSR) and attainment/unclassifiable areas (PSD).[5] As the requirements of subpart 4 only pertain to nonattainment areas, the EPA does not consider the portions of the 2008 rule that address requirements for $PM_{2.5}$ in attainment and unclassifiable areas to be affected by the court's opinion. Moreover, the EPA does not anticipate the need to revise any PSD requirements promulgated in the 2008 NSR $PM_{2.5}$ Implementation Rule in order to comply with the court's decision. Accordingly, the EPA's proposed approval of revisions to the Oklahoma SIP with respect to the PSD requirements promulgated by the 2008 NSR $PM_{2.5}$ Implementation Rule does not conflict with the court's opinion.

With respect to the nonattainment area requirements in affected rules, including the NNSR requirements of the 2008 $PM_{2.5}$ NSR Implementation Rule, on June 2, 2014, the EPA published a final rulemaking that begins to address the remand of both rules. *See* 79 FR 31566. The final rule classifies all existing 1997 and 2006 $PM_{2.5}$ NAAQS nonattainment areas as "Moderate" nonattainment areas and sets a deadline of December 31, 2014, for states to submit any SIP submissions, including nonattainment NSR SIPs, that may be necessary to satisfy the requirements of subpart 4, part D, title I of the CAA with respect to those 1997 and 2006 $PM_{2.5}$ NAAQS nonattainment areas.

In a separate rulemaking process that will follow the April 2014 rule, the EPA is evaluating the requirements of subpart 4 as they pertain to, among other things, nonattainment NSR for $PM_{2.5}$ emissions. In particular, subpart 4 includes section 189(e) of the CAA, which requires the control of major stationary sources of PM_{10} precursors "except where the Administrator determines that such sources do not contribute significantly to PM_{10} levels which exceed the standard in the area." Under the court's decision in *NRDC,* section 189(e) of the CAA also applies to $PM_{2.5}$.

Notably, Oklahoma does not have any areas designated as nonattainment under either the 1997 or the 2006 $PM_{2.5}$ NAAQS. The obligation for a state to submit a plan addressing $PM_{2.5}$ nonattainment NSR permitting requirements under CAA section 189(a)(1)–(2) only attaches when an area within a state has been designated nonattainment. Accordingly, Oklahoma is not required at this time to make any submissions addressing $PM_{2.5}$ nonattainment NSR permitting. The December 31, 2014, deadline for states to make any additional submission necessary to address the requirements of subpart 4 as to the 1997 and 2006 $PM_{2.5}$ NAAQS, including addressing the regulation of $PM_{2.5}$ precursors pursuant to section 189(e), does not apply to Oklahoma.

Nonetheless, as discussed above in our evaluation of the NNSR Definitions at OAC 252:100–8–51, the State of Oklahoma submitted a revision to the Oklahoma SIP on February 6, 2012, which included revisions to definitions in the Oklahoma NNSR Permitting Program to address $PM_{2.5}$. The revised definition of "regulated NSR pollutant" at OAC 252:100–8–51 is consistent with the federal definition of "regulated NSR pollutant" at 40 CFR 51.165(a)(1)(xxxvii) and identifies precursors to $PM_{2.5}$ in nonattainment areas. With respect to $PM_{2.5}$, the revised definition of "regulated pollutant" at OAC 252:100–8–51 identifies sulfur dioxide and nitrogen oxides as regulated $PM_{2.5}$ precursors while volatile organic compounds (VOCs) and ammonia are not regulated $PM_{2.5}$ precursors in $PM_{2.5}$ nonattainment areas in Oklahoma. The February 6, 2012, submittal incorporates by reference the definition of "significant" at 40 CFR 51.165(a)(1) as it exists on July 1, 2011, and will therefore include significant emission rates for direct $PM_{2.5}$ and for sulfur dioxide and nitrogen oxides as $PM_{2.5}$ precursors. These revisions, although consistent with the 2008 NSR Rule as developed consistent with subpart 1 of the Act, may not contain the elements necessary to satisfy the CAA requirements when evaluated under the subpart 4 statutory requirements in the event an area in Oklahoma is designated nonattainment in the future. In particular, Oklahoma's submission does not include regulation of VOCs and ammonia as $PM_{2.5}$ precursors, nor does it include a demonstration consistent with section 189(e) showing that major sources of those precursor pollutants would not contribute significantly to $PM_{2.5}$ levels exceeding the standard in the area. For these reasons, the EPA cannot conclude at this time that this part of the Oklahoma NNSR submission satisfies all of the requirements of subpart 4 as they pertain to $PM_{2.5}$ NNSR permitting. However, because $PM_{2.5}$

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[4] 706 F.3d 428 (D.C. Cir. 2013).

[5] The 2007 implementation rule also addressed by the *NRDC* decision does not address any NSR requirements and is therefore not addressed by this rulemaking.

levels in Oklahoma do not currently exceed the standard, it is not necessary for the Oklahoma NNSR SIP at this time to fully address the requirements under CAA section 189. In the event that an area is designated nonattainment for the 2012 $PM_{2.5}$ NAAQS or any other future $PM_{2.5}$ NAAQS, Oklahoma will have a deadline under section 189(a)(2) of the CAA to make a submission addressing the statutory requirements as to that area, including the requirements in section 189(e) that apply to the regulation of $PM_{2.5}$ precursors.

The revisions to Oklahoma's NNSR rule are not required by the statute at this time, nor do the revisions contain all of the necessary elements to satisfy the CAA requirements when evaluated under the subpart 4 provisions; however, the revisions represent an enhancement of the currently SIP-approved Oklahoma NNSR Permitting Program, which does not address $PM_{2.5}$ or its precursors at all. For these reasons, the EPA is proposing to approve the NNSR revisions at OAC 252:100–8–51 as submitted on February 6, 2012. We note that only SO_2 and NO_X will be regulated as $PM_{2.5}$ precursors under the Oklahoma NNSR program.

c. PSD for $PM_{2.5}$—Increments, SILs, and SMC Rule

The EPA finalized the PSD for $PM_{2.5}$—Increments, SILs and SMC Rule to provide additional regulatory requirements under the PSD SIP program regarding the implementation of the $PM_{2.5}$ NAAQS. *See* 75 FR 64864. The PSD for $PM_{2.5}$—Increments, SILs and SMC Rule required states to submit SIP revisions to EPA by July 20, 2012, adopting provisions equivalent to or at least as stringent as the $PM_{2.5}$ PSD increments and the associated implementing regulations promulgated pursuant to section 166(a) of the CAA. More detail on the PSD for $PM_{2.5}$—Increments, SILs and SMC Rule can be found in the EPA's October 20, 2010 final rule. *See* 75 FR 64864.

With respect to the requirement that revisions to the PSD program must include the increment component of the PSD for $PM_{2.5}$—Increments, SILs and SMC Rule, the ODEQ has adopted the required $PM_{2.5}$ increments at OAC 252:100–3–4 that are at least as stringent as those promulgated by the EPA on October 20, 2011. The ODEQ further adopted revisions to definitions of "baseline area," "major source baseline date," and "minor source baseline date" at OAC 252:100–8–31 that are required for the implementation of the $PM_{2.5}$ increment at least as stringent as regulations promulgated by the EPA on October 20, 2011. The ODEQ also correctly updated the source impact analysis requirements at OAC 252:100–8–35(a)(1) and the provisions for sources impacting Class I areas at OAC 252:100–8–36 consistent with the requirements at 40 CFR 51.166(k)(1) and 40 CFR 51.166(p), respectively, promulgated by the EPA on October 20, 2011. The EPA is proposing to find that the Oklahoma PSD program and the Oklahoma SIP now includes the required $PM_{2.5}$ increments and associated implementing regulations, and these provisions are applicable requirements for sources and modifications that are major for $PM_{2.5}$ and/or the identified precursors of SO_2 and NO_X.

With respect to the NNSR Program, the October 20, 2010 final rule also codified the $PM_{2.5}$ SILs in the EPA's regulations on new source review and permitting requirements at 40 CFR 51.165(b)(2). Unlike the PSD regulations (40 CFR 51.166 and 40 CFR 52.21), 40 CFR 51.165(b)(2) does not use the SILs to exempt a source from conducting cumulative air quality analysis. Instead, 40 CFR 51.165(b)(2) states that a proposed source or modification will be considered to cause a violation of a NAAQS when that source or modification would, at a minimum exceed the SIL in any area that does not or would not meet the applicable NAAQS. The revisions at OAC 252:100–8–52(a) incorporate by reference the federal requirements for SILs at 40 CFR 51.165(b)(2) as of December 20, 2010.

d. The EPA's Analysis of the Revisions to the Oklahoma PSD Program in Light of the Litigation on the October 20, 2010 PSD for $PM_{2.5}$—Increments, SILs and SMC Rule

The EPA's October 20, 2010 PSD for $PM_{2.5}$—Increments, SILs and SMC Rule also provided that states could discretionarily choose to adopt and submit for EPA approval $PM_{2.5}$ SILs, used as a screening tool to evaluate the impact a proposed new major source or major modification may have on the NAAQS or PSD increment, and/or a $PM_{2.5}$ SMC (also a screening tool) to determine the subsequent level of ambient air monitoring data gathering required for a PSD permit application for emissions of $PM_{2.5}$.

On January 22, 2013, the U.S. Court of Appeals for the District of Columbia granted a request from the EPA to vacate and remand to the EPA portions of the federal PSD regulations (40 CFR 51.166(k)(2) and 52.21(k)(2)) setting forth provisions for implementing SILs for $PM_{2.5}$ so that the EPA could reconcile the inconsistency between the regulatory text and certain statements in the preamble to the 2010 final rule. *Sierra Club* v. *EPA,* 705 F.3d 458, 463–64 (D.C. Cir. 2013). The court declined to vacate the different portions of the federal PSD regulations (40 CFR 51.165(b)(2)) for implementing SILs for $PM_{2.5}$ that did not contain the same inconsistency in the regulatory text. *Id.* at 465–66. The court further vacated the portions of the PSD regulations (40 CFR 51.166(i)(5)(i)(*c*) and 52.21(i)(5)(i)(*c*)) implementing a $PM_{2.5}$ SMC, finding that the EPA lacked legal authority to adopt and use the $PM_{2.5}$ SMC to exempt permit applicants from the statutory requirement to compile and submit ambient monitoring data. *Id.* at 468–69. On December 9, 2013, the EPA issued a good cause final rule formally removing the affected PSD SILs and SMC provisions from the CFR. *See* 78 FR 73698.

Oklahoma has adopted and submitted provisions to establish the $PM_{2.5}$ SIL at OAC 252:100–8–35(a)(2) and the $PM_{2.5}$ SMC at OAC 252:100–8–33(c)(1)(C) in the Oklahoma PSD program. The EPA is severing these discretionary provisions from this action; we will address these submitted provisions in a separate action at a later date.

The court ruling and the EPA's subsequent good cause final rulemaking only addressed the PSD revisions of the October 20, 2010, final rule; therefore there will be no impact on the submitted revisions to the Oklahoma NNSR program.

5. EPA's GHG Tailoring Rule

On June 3, 2010, the EPA published a final rule, known as the Tailoring Rule, which phased in permitting requirements for greenhouse gas (GHG) emissions from stationary sources under the CAA PSD and title V permitting programs (75 FR 31514). Under its interpretation of the CAA at the time, the EPA believed the Tailoring Rule was necessary to avoid a sudden and unmanageable increase in the number of sources that would be required to obtain PSD and title V permits under the CAA because the sources emitted or had the potential to emit GHGs above the applicable major source and major modification thresholds.

In Step 1 of the Tailoring Rule, which began on January 2, 2011, the EPA limited application of PSD and title V requirements for GHGs to sources that were subject to PSD or title V "anyway" due to their emissions of non-GHG pollutants. These sources are referred to as "anyway sources." In Step 2 of the Tailoring Rule, which began on July 1, 2011, the EPA applied the PSD and title V permitting requirements under the CAA to sources that were classified as major, and, thus, required to obtain a permit, based solely on their GHG emissions or potential to emit GHGs, and to modifications of major sources that required a PSD permit because they increased only GHG emissions above the threshold level in the EPA regulations. On June 23, 2014, the U.S. Supreme Court issued a decision in *Utility Air Regulatory Group (UARG)* v. *EPA*, 134 S. Ct. 2427, addressing the application of stationary source permitting requirements to GHGs. The U.S. Supreme Court held that the EPA may not treat GHGs as an air pollutant for the specific purpose of determining whether a source is a major source (or a modification thereof) and thus required to obtain a PSD or title V permit. With respect to PSD, the ruling effectively upheld the PSD permitting requirements for GHG emissions under Step 1 of the Tailoring Rule for "anyway sources," and invalidated the PSD permitting requirements for Step 2 sources. Because the Supreme Court decision affirmed in part and reversed in part an earlier decision of the D.C. Circuit in *Coalition for Responsible Regulation* v. *EPA*, 684 F.3d 102 (D.C. Cir. 2012), on April 10, 2015, the D.C. Circuit issued an Amended Judgment (Nos. 09–1322, 10–073, 10–1092 and 10–1167), which reflects the *UARG* v. *EPA* Supreme Court decision. The D.C. Circuit simultaneously issued its mandate, which means that the *Coalition* Amended Judgment became final and effective upon issuance. In the *Coalition* Amended Judgment, the D.C. Circuit ordered that the EPA regulations under review (including 40 CFR 51.166(b)(48)(v) and 40 CFR 52.21(b)(49)(v)) be vacated to the extent they require a stationary source to obtain a PSD permit if GHGs are the only pollutant (i) that the source emits or has the potential to emit above the applicable major source thresholds, or (ii) for which there is a significant emissions increase from a modification. The D.C. Circuit also ordered that the regulations under review be vacated to the extent they require a stationary source to obtain a title V permit solely because the source emits or has the potential to emit GHGs above the applicable major source thresholds, and that the EPA consider further phasing in the GHG permitting requirements at lower GHG emission thresholds (in particular 40 CFR 52.22 and 40 CFR 70.12, 71.13).

In response to the *Coalition* Amended Judgment, the EPA promulgated a good cause final rule on August 19, 2015, removing the PSD permitting provisions for Step 2, non-anyway sources from the federal regulations at 40 CFR 51.166(b)(48)(v) and 52.21(b)(49)(v). The EPA no longer has the authority to regulate Step 2, non-anyway sources, nor can we approve provisions in a state regulation providing this authority. We anticipate future federal rulemakings to address the remainder of the UARG and Coalition judgments. We further anticipate that these federal rulemaking actions will necessitate revisions to the existing PSD regulations in SIP-approved states.

The ODEQ submitted revisions to the Oklahoma SIP addressing the regulation and permitting of GHGs on February 6, 2012 and January 18, 2013. The EPA finds that the provisions for Step 1 permitting submitted on February 6, 2012, at OAC 252:100–8–31, definition of "subject to regulation," subparagraphs (A), (B), (C), (D), and (F) are consistent with federal requirements for Step 1 GHG Permitting at 40 CFR 51.166(b)(48). Additionally, the February 6, 2012 submittal included revisions to the general definitions at OAC 252:100–1–3 to include new definitions for CO_2e and GHG consistent with the federal PSD definitions at 40 CFR 51.166(b)(48)(ii)(*a*) and 51.166(b)(48)(i), respectively.

On May 23, 2016, the EPA promulgated our final disapproval of the provisions for Step 2 permitting submitted on February 6, 2012 and the revisions submitted on January 18, 2013 to implement the GHG Biomass Deferral. *See* 81 FR 32239.

a. EPA's Analysis of the Approvability of the Oklahoma PSD Automatic Rescission Provisions for GHGs

Oklahoma's February 6, 2012, SIP submittal adds automatic rescission provisions to the State's PSD regulations at OAC 252:8–100–36.2, definition of "subject to regulation," subparagraph (F). The automatic rescission provisions provide that in the event that federal legislation or a federal court determines that a portion of the EPA's tailoring rule, endangerment finding, or light-duty vehicle GHG standard is unenforceable, that provision will be enforceable in the Oklahoma PSD program only to the extent that it is enforceable by the EPA.

The EPA is proposing to approve the Oklahoma automatic rescission provisions. In assessing the approvability of this severability provision, the EPA considers two key factors: (1) Whether the public will be given reasonable notice of any change to the SIP that occurs as a result of the automatic rescission provisions, and (2) whether any future change to the SIP that occurs as a result of the automatic rescission provisions would be consistent with the EPA's interpretation of the effect of the triggering action on federal GHG permitting requirements. *See e.g.*, 79 FR 8130 (February 11, 2014) and 77 FR 12484 (March 1, 2012). These criteria are derived from the SIP revision procedures set forth in the CAA and federal regulations.

Regarding public notice, CAA section 110(l) provides that any revision to a SIP submitted by a State to EPA for approval "shall be adopted by such State after reasonable notice and public hearing." In accordance with CAA section 110(l), ODEQ followed applicable notice-and-comment procedures prior to adopting the automatic rescission provisions. Thus, the public is on notice that the automatic rescission provisions in the Oklahoma PSD program will enable the Oklahoma PSD program and the Oklahoma SIP to update automatically to reflect any order by a federal court or any change in federal law that limits or renders ineffective the regulation of GHGs under the CAA's PSD permitting program. In a letter dated April 22, 2016, the ODEQ has stated that it would provide notice to the general public and regulated community of the changes to the Oklahoma PSD program in the event of any change in the federal permitting requirements for GHGs.

The EPA's consideration of whether any SIP change resulting from Oklahoma's automatic rescission provisions would be consistent with our interpretation of the effect of the triggering action on federal GHG permitting requirements is based on 40 CFR 51.105, which states that "[r]evisions of a plan, or any portion thereof, will not be considered part of an applicable plan until such revisions have been approved by the Administrator in accordance with this part." To be consistent with 40 CFR 51.105, any automatic SIP change resulting from a court order or federal law change must be consistent with the EPA's interpretation of the effect of such order or federal law change on GHG permitting requirements. We interpret this provision to mean that Oklahoma will wait for and follow the EPA's interpretation as to the impact of any federal law change or the D.C. Circuit or the U.S. Supreme Court issues an order before Oklahoma's SIP would be changed. In the event of a court decision or federal law change that triggers (or likely triggers) application of Oklahoma's automatic rescission provisions, the EPA intends to promptly describe the impact of the court decision or federal law change on the enforceability of its GHG permitting regulations. The EPA invites comment, particularly from the State, regarding this interpretation.

6. PSD and NNSR: Reconsideration of Inclusion of Fugitive Rule and Subsequent EPA-Stays

On December 19, 2008, the EPA issued a final rule revising the requirements of PSD and NNSR program regarding the treatment of fugitive emissions (Fugitive Emissions Rule, 73 FR 77882). The Fugitive Emissions Rule required fugitive emissions to be included in determining whether a physical or operational change results in a major modification only for sources in industries that have been designated through rulemaking under section 302(j) of the CAA. Previously, the EPA rules required that fugitive emissions be included in major modification applicable determinations for all source categories.

On February 17, 2009, the Natural Resources Defense Council (NRDC) submitted a petition for reconsideration of the December 2008 Fugitive Emissions Rule. On April 24, 2009, the EPA responded to the petition by letter indicating we were convening a reconsideration proceeding for the December 2008 Fugitive Emissions Rule and granted a 3-month administrative stay of the rule provisions. The initial 3-month administrative stay of the Fugitive Emissions Rule became effective on September 30, 2009. *See* 74 FR 50115. An interim final rule extending the administrative stay for an additional 3 months became effective on December 31, 2009. *See* 74 FR 5265692. An additional 18 month stay was finalized on March 31, 2010. *See* 75 FR 16012. The EPA finalized a final rule on March 30, 2011, titled PSD and NNSR: Reconsideration of Inclusion of Fugitive Rule. *See* 76 FR 17548. This final action stayed indefinitely the provisions of the December 2008 Fugitive Emissions Rule. As such, the Oklahoma PSD and NNSR programs must consider fugitive emissions in the major modification applicability determinations for all source categories.

Following is a summary of how the Oklahoma PSD program addresses fugitive emissions consistent with the current PSD requirements.

- The Oklahoma PSD program does not include the revisions to "major modification" or "net emissions increase" promulgated by the EPA in the December 2008 Fugitive Emissions Rule at 40 CFR 51.166(b)(2)(v) or 40 CFR 51.166(b)(3)(iii)(*d*), respectively. As such, the Oklahoma PSD program does not include the provisions that are indefinitely stayed.
- The Oklahoma PSD program continues to require fugitive emissions to be included in the major modification applicability determinations for all source categories.
- The Oklahoma SIP at OAC 252:100–1–3 includes the definition of "fugitive emissions" consistent with the federal definition at 40 CFR 51.166(b)(20).
- The definition of "projected actual emissions" at OAC 252:100–8–31 in the Oklahoma PSD program has been revised to include fugitive emissions to the extent quantifiable and emissions associated with startups, shutdowns, and malfunctions. This definition has also been revised to allow for the use of the emission unit's potential to emit in TPY consistent with 40 CFR 51.166(b)(40)(ii)(b) and (d).
- The definition of "baseline actual emissions" at OAC 252:100–8–31 in the Oklahoma PSD program has been revised to include fugitive emissions to the extent quantifiable for any existing electric utility steam generating unit (EUSGU) and any existing emissions unit other than an EUSGU consistent with 40 CFR 51.166(b)(47)(i)(a) and (ii)(a). This definition has also been revised to address the requirements for calculating baseline actual emissions for a new emissions unit consistent with 40 CFR 51.166(b)(47)(iii). This definition has also been revised to address the requirements for calculating baseline actual emissions or a PAL consistent with 40 CFR 51.166(b)(47)(iv).
- The Oklahoma SIP at OAC 252:100–8–33(a)(1)(B) includes the exemption at 40 CFR 51.166(i)(1)(ii).
- The source obligation provisions at OAC 252:100–8–36.2(c) for the requirements when using projected actual emissions are consistent with the obligation provisions found at 40 CFR 51.166(r)(6)(i)–(v). Note that the Oklahoma PSD program does not include the reasonable possibility provisions at 40 CFR 51.166(r)(6)(vi). Rather, the Oklahoma PSD program requires all sources using the "projected actual emissions" methodology to maintain records consistent with 40 CFR 51.166(r)(6). This is more stringent than federal requirements and is therefore approvable.
- The Oklahoma PSD program incorporates by reference the PSD PALs provisions at 40 CFR 51.166(w) as of July 2, 2007. However, the definition of "baseline actual emissions" for PALs is not part of this incorporation by reference. Per OAC 252:100–8–31 definition of "baseline actual emissions," paragraph (E) for a PAL stationary source, the baseline actual emissions for an EUSGU or other existing emissions units other than an EUSGU shall be calculated using the general Oklahoma PSD definition of "baseline actual emissions" at OAC 252:100–8–31 and therefore will include fugitive emissions to the extent quantifiable.

Following is a summary of how the Oklahoma NNSR program addresses fugitive emissions.

- The Oklahoma NNSR program does not include the revisions to "major modification" or "net emissions increase" promulgated by the EPA in the December 2008 Fugitive Emissions Rule at 40 CFR 51.165(a)(1)(v)(G) or 40 CFR 51.165(a)(1)(vi)(C)(3), respectively. As such, the Oklahoma NNSR program does not include the provisions that are indefinitely stayed.
- The Oklahoma NNSR program continues to require fugitive emissions to be included in the major modification applicability determinations for all source categories.
- The Oklahoma NNSR program at OAC 252:100–8–51 incorporates by reference the federal NNSR definitions for "major stationary source," "fugitive emissions," and "projected actual emissions" as of July 1, 2010. The Oklahoma NNSR program does not IBR the definition of "baseline actual emissions," rather the NNSR program relies on the Oklahoma PSD definition at OAC 252:100–8–31 for the definition of "baseline actual emissions."
- The applicability provisions at OAC 252:100–8–50 have been evaluated elsewhere in this TSD and determined to be consistent with federal requirements for NNSR.
- The Oklahoma NNSR program at OAC 252:100–8–53 incorporates by reference the requirements of 40 CFR 51.165(a)(4) regarding the exemption of fugitive emissions in determining whether a source or modification is major as of July 2, 2007. The Oklahoma NNSR program source obligations at OAC 252:100–8–55 incorporates by reference the requirements of 40 CFR 51.165(a)(6)(i) through (v) as of July 2, 2007. Additionally the Oklahoma NNSR program at OAC 252:100–8–57 incorporates by reference the requirements at 40 CFR 51.165(f) regarding actuals PALs as of July 2, 2007.

D. Evaluation Under Section 110(l) of the CAA

Under Section 110(l), the EPA cannot propose to approve a SIP revision that has not been developed with reasonable notice and public hearing. Nor can we propose to approve a revision that will worsen air quality. The submitted revisions to the Oklahoma SIP were developed using the Oklahoma SIP-approved process with adequate notice and comment procedures. Our analysis also indicates that the revisions to the major source PSD and NNSR permitting programs are necessary to maintain consistency with federal permitting requirements. The revisions to the general Oklahoma SIP requirements are necessary to implement the major source permitting programs. As such, we find that the revisions to the Oklahoma PSD and NNSR programs and the General SIP requirements will support the state's air quality programs and will not interfere with attainment, reasonable further progress or any other applicable requirements of the CAA. Therefore, the EPA proposes to find that the revisions to the Oklahoma SIP submitted on June 24, 2010; July 16, 2010; December 27, 2010; February 6, 2012; and January 18, 2013 will not result in degradation of air quality.

III. Proposed Action

For the reasons presented above and in our accompanying TSD, the EPA proposes to approve the severable revisions to the Oklahoma SIP submitted on June 24, 2010; July 16, 2010; December 27, 2010; February 6, 2012; and January 18, 2013. We have made the preliminary determination that the revisions were developed and submitted in accordance with the requirements of the CAA and the EPA's regulations regarding SIP development at 40 CFR part 51. Additionally, we have determined that the submitted revisions to the Oklahoma PSD and NNSR programs are consistent with our major source permitting regulations at 40 CFR 51.160–51.166 and the associated policy and guidance. Therefore, under section 110 and parts C and D of the Act, the EPA proposes to fully approve into the Oklahoma SIP the following revisions:

TABLE 1—REVISIONS TO THE OKLAHOMA SIP PROPOSED FOR APPROVAL

Section	Title	Effective date	Submittal date
OAC 252:100–1–1	General Provisions, Purpose	June 12, 2003	July 16, 2010.
OAC 252:100–1–2	General Provisions, Statutory definitions	June 12, 2003	July 16, 2010.
OAC 252:100–1–3	General Provisions, Definitions	June 12, 2003	July 16, 2010.
		July 1, 2008	July 16, 2010.
		July 1, 2009	July 16, 2010.
		June 15, 2006	July 16, 2010.
		July 1, 2011	February 6, 2012.
		July 1, 2012	January 18, 2013.
OAC 252:100–1–4	General Provisions, Units, Abbreviations and acronyms.	June 12, 2003	July 16, 2010.
		July 1, 2009	July 16, 2010.
		July 1, 2011	February 6, 2012.
OAC 252:100–2–1	Incorporation by Reference (IBR) Purpose	July 1, 2012	January 18, 2013.
OAC 252:100–2–3	IBR, Incorporation by Reference	July 1, 2012	January 18, 2013.
OAC 252:100–3–4	Air Quality Standards and Increments, Significant Deterioration Increments.	June 15, 2005	December 27, 2010.
		July 1, 2011	February 6, 2012.
OAC 252:100, Appendix P	Regulated Air Pollutants	June 15, 2007	July 16, 2010.
OAC 252:100, Appendix Q	Incorporation by Reference	July 1, 2009	July 16, 2010.
		July 1, 2012	January 18, 2013.
OAC 252:100–5–1.1	Definitions	June 15, 2007	July 16, 2010.
OAC 252:100–5–2.1	Emission Inventory	June 11, 2004	July 16, 2010.
		June 15, 2007	July 16, 2010
OAC 252:100–8–1.1	General Provisions, Definitions	June 15, 2006	July 16, 2010.
OAC 252:100–8–30	Prevention of Significant Deterioration (PSD) Requirements for Attainment Areas, Applicability.	June 1, 2009	June 24, 2010.
		June 15, 2006	July 16, 2010.
OAC 252:100–8–31	PSD, Definitions	June 1, 2009	June 24, 2010.
		June 15, 2006	July 16, 2010.
		July 1, 2011	February 6, 2012.
		July 1, 2012	January 18, 2013.
OAC 252:100–8–32	PSD, Source Applicability Determination	REVOKED June 15, 2006.	REVOKED July 16, 2010.
OAC 252:100–8–32.1	PSD Ambient Air Increments and Ceilings	June 15, 2006	July 16, 2010.
OAC 252:100–8–32.2	PSD Exclusion from Increment Consumption.	June 15, 2006	July 16, 2010.
OAC 252:100–8–32.3	PSD Stack Heights	June 15, 2006	July 16, 2010.
OAC 252:100–8–33	PSD, Exemptions	June 1, 2009	June 24, 2010.
		June 15, 2006	July 16, 2010.
		July 1, 2011	February 6, 2012.
		July 1, 2012	January 18, 2013.
OAC 252:100–8–34	PSD, Control Technology Review	June 15, 2006	July 16, 2010.
OAC 252:100–8–35	PSD Air Quality Impact Evaluation	June 15, 2006	July 16, 2010.
		July 1, 2011	February 6, 2012.
OAC 252:100–8–35.1	PSD Source Information	June 15, 2006	July 16, 2010.
OAC 252:100–8–35.2	PSD Additional Impact Analyses	June 15, 2006	July 16, 2010.
OAC 252:100–8–36	PSD Source Impacting Class I Areas	June 15, 2006	July 16, 2010.
OAC 252:100–8–36.2	PSD Source Obligation	June 15, 2006	July 16, 2010.
OAC 252:100–8–37	PSD, Innovative Control Technology	June 1, 2009	June 24, 2010.
		June 15, 2006	July 16, 2010.
OAC 252:100–8–38	PSD, Actuals PAL	June 1, 2009	June 24, 2010.
		June 15, 2006	July 16, 2010.
OAC 252:100–8–39	PSD Severability	June 15, 2006	July 16, 2010.
OAC 252:100–8–50	Majors Affecting Nonattainment Areas (NNSR), Applicability.	June 1, 2009	June 24, 2010.
		June 15, 2006	July 16, 2010.

TABLE 1—REVISIONS TO THE OKLAHOMA SIP PROPOSED FOR APPROVAL—Continued

Section	Title	Effective date	Submittal date
OAC 252:100–8–50.1	NNSR, Incorporation by Reference	June 1, 2009 June 15, 2006 July 1, 2011	June 24, 2010. July 16, 2010. February 6, 2012.
OAC 252:100–8–51	NNSR, Definitions	June 1, 2009 June 15, 2006 July 1, 2011	June 24, 2010. July 16, 2010. February 6, 2012.
OAC 252:100–8–51.1	NNSR Emission reductions and offsets	June 15, 2006 July 1, 2011 July 1, 2012	July 16, 2010. February 6, 2012. January 18, 2013.
OAC 252:100–8–52	NNSR, Applicability determination for sources in attainment areas causing or contributing to NAAQS violations.	June 1, 2009 June 15, 2006 July 1, 2011	June 24, 2010. July 16, 2010. February 6, 2012.
OAC 252:100–8–53	NNSR, Exemptions	June 1, 2009 June 15, 2006	June 24, 2010. July 16, 2010.
OAC 252:100–8–54	NNSR Requirements for sources located in nonattainment areas.	June 15, 2006	July 16, 2010.
OAC 252:100–8–54.1	NNSR, Ozone and PM_{10} precursors	June 1, 2009	June 24, 2010.
OAC 252:100–8–55	NNSR, Source Obligation	June 1, 2009 June 15, 2006	June 24, 2010. July 16, 2010.
OAC 252:100–8–56	NNSR, Actuals PAL	June 1, 2009 June 15, 2006	June 24, 2010. July 16, 2010.
OAC 252:100–8–57	NNSR Severability	June 15, 2006	July 16, 2010.

Upon promulgation of a final approval of the proposed revisions to address the GHG Step 1 permitting requirements, the EPA would also remove the provisions at 40 CFR 52.1929(c), under which the EPA narrowed the applicability of the Oklahoma PSD program to regulate sources consistent with federal requirements. The provisions at 40 CFR 52.1929(c) will no longer be necessary when we finalize approval of the State regulations into the Oklahoma SIP.

The EPA is proposing to find that the February 6, 2012, revisions to the Oklahoma NNSR program address all required NNSR elements for the implementation of the 1997 and 2006 $PM_{2.5}$ NAAQS. We note that the Oklahoma NNSR program does not include regulation of VOCs and ammonia as $PM_{2.5}$ precursors. However, as section 189(e) of the Act requires regulation of $PM_{2.5}$ precursors that significantly contribute to $PM_{2.5}$ levels "which exceed the standard in the area" and Oklahoma does not have a designated $PM_{2.5}$ nonattainment area, the revisions addressing only SO_2 and NO_X are not inconsistent with the requirements of the CAA. In the event that an area is designated nonattainment for the 2012 $PM_{2.5}$ NAAQS, or any other future $PM_{2.5}$ NAAQS, Oklahoma will have a deadline under section 189(a)(2) of the CAA to make a submission addressing the statutory requirements as to that area, including the requirements in section 189(e) that apply to the regulation of $PM_{2.5}$ precursors.

The EPA is also proposing a ministerial correction to 40 CFR 52.1920(c) to remove a duplicate entry for the SIP approval of OAC 252:100–5–1. We propose to remove the first listing of this section, and retain the identical entry in numerical order under OAC, Title 252, Subchapter 5—Registration, Emissions Inventory, and Annual Operating Fees.

The EPA invites the public to make comments on all aspects of our proposed full approval of the revisions to the Oklahoma SIP as presented above and to submit them by the indicated Date. After reviewing the comments received, we will make a final determination of the approvability of the specified revisions to the Oklahoma SIP in the **Federal Register**.

IV. Incorporation by Reference

In this action, we are proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are proposing to incorporate by reference revisions to the Oklahoma regulations as described in the Proposed Action section above. We have made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the EPA Region 6 office.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because

application of those requirements would be inconsistent with the CAA; and

- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 22, 2016.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2016–15618 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2015–0522; FRL–9948–51–Region 5]

Air Plan Approval; Ohio; Removal of Stage II Gasoline Vapor Recovery Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the Ohio Environmental Protection Agency (Ohio EPA) on July 15, 2015 and February 29, 2016, concerning the state's Stage II vapor recovery (Stage II) program for the Cleveland, Cincinnati, and Dayton ozone areas in Ohio. The revision removes Stage II requirements for the three areas as a component of the Ohio ozone SIP. The submittal also includes a demonstration as required by the Clean Air Act (CAA) that addresses emissions impacts associated with the removal of the program.

DATES: Comments must be received on or before August 1, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0522 at *http://www.regulations.gov,* or via email to *persoon.carolyn@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the "For Further Information Contact" section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Francisco J. Acevedo, Mobile Source Program Manager, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6061, *acevedo.francisco@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

I. Background
II. What changes have been made to the Ohio Stage II vapor recovery program?
III. What is EPA's analysis of the state's submittal?
IV. What action is EPA proposing to take?
V. Incorporation by Reference
VI. Statutory and Executive Order Reviews

I. Background

Stage II and onboard refueling vapor recovery systems (ORVR) are two types of emission control systems that capture fuel vapors from vehicle gas tanks during refueling. Stage II systems are specifically installed at gasoline dispensing facilities (GDF) and capture the refueling fuel vapors at the gasoline pump nozzle. The system carries the vapors back to the underground storage tank at the GDF to prevent the vapors from escaping to the atmosphere. ORVR systems are carbon canisters installed directly on automobiles to capture the fuel vapors evacuated from the gasoline tank before they reach the nozzle. The fuel vapors captured in the carbon canisters are then combusted in the engine when the automobile is in operation. Stage II and vehicle ORVR were initially both required by the 1990 Amendments to the CAA under sections 182(b)(3) and 202(a)(6), respectively. In some areas Stage II has been in place for over 25 years, but Stage II was not widely implemented by the states until the early to mid-1990s as a result of the CAA requirements for moderate, serious, severe, and extreme ozone nonattainment areas, and for states in the Northeast Ozone Transport Region (OTR) under CAA section 184(b)(2).

CAA section 202(a)(6) required EPA to promulgate regulations for ORVR for light-duty vehicles (passenger cars). EPA adopted these requirements in 1994, at which point moderate ozone nonattainment areas were no longer subject to the section 182(b)(3) Stage II requirement. However, some moderate areas retained Stage II requirements to provide a control method to comply with rate-of-progress emission reduction targets. ORVR equipment has been phased in for new passenger vehicles beginning with model year 1998, and starting in 2001 for light-duty trucks and most heavy-duty gasoline-powered vehicles. ORVR equipment has been installed on nearly all new gasoline-powered light-duty vehicles, light-duty trucks and heavy-duty vehicles since 2006.

During the phase-in of ORVR controls, Stage II has provided volatile organic compound (VOC) reductions in ozone nonattainment areas and certain attainment areas of the OTR. Congress recognized that ORVR and Stage II would eventually become largely redundant technologies, and provided authority to EPA to allow states to remove Stage II from their SIPs after EPA finds that ORVR is in widespread use.

Effective May 16, 2012 (77 FR 28772), EPA determined that ORVR is in widespread nationwide use for control of gasoline emissions during refueling of vehicles at GDFs. Currently, more than 75 percent of gasoline refueling nationwide occurs with ORVR-equipped vehicles, so Stage II programs have become largely redundant control systems and Stage II systems achieve an ever declining emissions benefit as more ORVR-equipped vehicles continue to enter the on-road motor vehicle fleet.[1]

EPA also exercised its authority under CAA section 202(a)(6) to waive certain Federal statutory requirements for Stage II gasoline vapor recovery at GDFs. This decision exempts all new ozone nonattainment areas classified serious or above from the requirement to adopt Stage II control programs. Similarly, any state currently implementing Stage II programs may submit SIP revisions that, once approved by EPA, would allow for the phase out of Stage II control systems. To assist states in the development of SIP revisions to remove Stage II requirements from their SIPs, EPA released its "Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures" (EPA–457/B–12–001) on August 7, 2012.

II. What changes have been made to the Ohio Stage II vapor recovery program?

The Ohio EPA originally submitted a SIP revision to EPA on June 7, 1993, to satisfy the requirement of section 182(b)(3) of the CAA. The revision applied to the Cleveland (Ashtabula, Cuyahoga, Geauga, Lake, Lorain, Medina, Portage and Summit counties), Cincinnati (Butler, Clermont, Hamilton and Warren counties), and Dayton (Clark, Greene, Miami and Montgomery counties) ozone nonattainment areas in Ohio. EPA partially approved Ohio's Stage II program on October 20, 1994 (59 FR 52911), including the program's legal authority and administrative requirements found in the Ohio Administrative Code (OAC) rules 3745–21–09 (DDD)(1)–(4).

As a result of EPA's May 16, 2012 determination that ORVR is in widespread nationwide use for control of gasoline emissions during refueling of vehicles at GDFs, Ohio EPA initiated a rulemaking process to revise its SIP to remove Stage II requirements for all facilities in the Cleveland, Cincinnati and Dayton areas. As part of that rulemaking process, an Ohio-specific analysis following EPA's recommended methodology was also completed. The analysis concluded that, starting in calendar year 2017, ORVR would be in widespread use in Ohio and that there would be no remaining emissions reduction benefit from Stage II requirements beyond the benefits from ORVR.

On July 15, 2015, and February 29, 2016, the Ohio EPA submitted a SIP revision requesting EPA approval of amendments to OAC 3745–21–09 (DDD) that removes Stage II requirements from the Ohio ozone SIP and allows GDFs currently implementing Stage II in the Cleveland, Cincinnati and Dayton areas to decommission their systems by 2017. To support the removal of the Stage II requirements, the revision included amended copies of OAC 3745–21–09 (DDD), as adopted on April 29, 2013, and January 17, 2014; a summary of Ohio-specific calculations based on EPA guidance used to calculate program benefits and demonstrate widespread use of ORVR in Ohio; and a section 110(l) demonstration that includes documentation that addresses the period, 2013–2017, when Stage II requirements were waived in Ohio but widespread use of ORVR has not yet occurred.

III. What is EPA's analysis of the state's submittal?

EPA's primary consideration for determining the approvability of Ohio's request is whether this requested action complies with section 110(l) of the CAA.[2]

Section 110(l) requires that a revision to the SIP not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of the Act. EPA evaluates each section 110(l) noninterference demonstration on a case-by-case basis considering the circumstances of each SIP revision. EPA interprets 110(l) as applying to all national ambient air quality standards (NAAQS) that are in effect, including those that have been promulgated but for which EPA has not yet made designations. The degree of the analysis focused on any particular NAAQS in a noninterference demonstration varies depending on the nature of the emissions associated with the proposed SIP revision.

In its July 15, 2015, and February 29, 2016, SIP revision, the Ohio EPA used EPA's guidance to conduct a series of calculations to determine the potential impact of removing the Stage II program on air quality.[3] Ohio EPA's analysis focused on VOC emissions because, as mentioned previously, Stage II requirements affect VOC emissions and because VOCs are a precursor for ground-level ozone formation.[4]

Ohio EPA has calculated that beginning in 2017, ORVR will be in widespread use in all three program areas and the absence of the Ohio Stage II program starting in 2017 would not result in a net VOC emissions increase compared to the continued utilization of this emissions control technology. The emission reduction losses resulting from removing Stage II before 2017 are transitional and relatively small since ORVR-equipped vehicles will continue to phase into the fleet over the coming years. Ohio EPA's calculation indicates a maximum potential loss of 1.858 tons per summer day (tpsd) in Cleveland, 0.914 tpsd in Cincinnati, and 0.655 tpsd in Dayton from 2013 through 2016. In 2013, the year with the highest level of emission increases, these summer day emissions increases are only 0.21 percent to 0.26 percent of the typical summer day VOC emissions rate in the three areas. These emissions increases are insignificant with respect to the total summer day VOC emission rates of all sectors in these areas. Also it is important to note that the minimal emissions increase significantly decreases over the next two years (2014 and 2015) and becomes an emissions decrease in 2017 and all years thereafter.

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[1] In areas where certain types of vacuum-assist Stage II systems are used, the differences in operational design characteristics between ORVR and some configurations of these Stage II systems result in the reduction of overall control system efficiency compared to what could have been achieved relative to the individual control efficiencies of either ORVR or Stage II emissions from the vehicle fuel tank.

[2] CAA section 193 is not relevant because Ohio's Stage II rule was not included in the SIP before the 1990 CAA amendments.

[3] EPA, Guidance on Removing Stage II Gasoline Vapor Control Program from State Implementation Plans and Assessing Comparable Measure, EPA–457/B–12–001 (August 7, 2012), available at: *http://www.epa.gov/groundlevelozone/pdfs/20120807guidance.pdf*. This guidance document notes that "the potential emission control losses from removing Stage II vapor recovery systems (VRS) are transitional and relatively small. ORVR-equipped vehicles will continue to phase in to the fleet over the coming years and will exceed 80 percent for all highway gasoline vehicles and 85 percent of all gasoline dispensed during 2015. As the number of these ORVE-equipped vehicles increase, the control of attributed to Stage II VRS will decrease even further, and the potential foregone Stage II VOC emission reductions are generally expected to be no more than one percent of the VOC inventory in the area."

[4] Cleveland is currently designated nonattainment for the 2012 Annual fine particulate matter ($PM_{2.5}$) NAAQS. While VOC is one of the precursors for $PM_{2.5}$ formation, a study (Journal of Environmental Engineering—Qualifying the sources of ozone, fine particulate matter, and regional haze in the Southeastern United States, June 24, 2009, available at: *http://www.journals.elsevier.com/journal-ofenvironmental-management*) indicates that in portions the Midwest (including portions of Ohio) where Stage II has been implemented, emissions of $PM_{2.5}$ and the precursor sulfur dioxide (SO_2) are more significant to ambient $PM_{2.5}$ concentrations than nitrogen oxides (NOx) and VOC. Specifically, $PM_{2.5}$ sensitivities to anthropogenic VOC emissions are near zero for the entire region, including the Cincinnati region. This study also indicated that the impact of SO_2 emission, especially from electric generating units, was most significant in the Cincinnati area due to SO_2 emissions in the entire mid-west region (Wisconsin, Illinois, Indiana, Michigan, and Ohio). In fact, emissions from the mid-west had the largest effect in the Cleveland and Dayton areas. The technical analysis has met EPA's guidance and demonstrates anthropogenic VOCs are insignificant to the formation of $PM_{2.5}$ in these areas. Currently, the Cleveland area is also designated nonattainment for sulfur dioxide (Lake Co.) and lead (Cuyahoga Co.) and those pollutants are not affected by the removal of Stage II requirements.

To help offset the initial emissions increases during the Stage II phase out period, Ohio EPA is requiring the installation of low permeation hoses at GDFs. Ohio EPA has calculated that low permeation hoses will provide 42.9 tons of VOC emission reductions each year during the ozone seasons (21.4 tons for Cleveland area, 13.6 tons for Cincinnati area, and 7.9 for Dayton area) starting in 2013. Table 1 shows the increase of emissions associated with the phase out of State II systems at facilities in all program areas in Ohio starting in 2013, as well as offset emissions associated with the requirement of low permeation hoses at GDFs.

TABLE 1—VOC EMISSIONS DURING OZONE SEASON

[Tons per day]

	2013	2014	2015	2016	2017
Cleveland Area					
Stage II Phase-out	0.910	0.580	0.300	0.068	−0.116
Low Permeation Hoses	−0.14	−0.14	−0.14	−0.14	−0.14
Daily Total	0.77	0.44	0.16	−0.072	−0.26
Typical Summer Day	367.17	367.17	367.17	367.17	367.17
% of Summer Day	0.21%	0.12%	0.043%	−0.019%	−0.26%
Cincinnati Area					
Stage II Phase-out	0.440	0.284	0.151	0.039	−0.053
Low Permeation Hoses	−0.089	−0.089	−0.089	−0.089	−0.089
Daily Total	0.35	0.20	0.062	−0.050	−0.14
Typical Summer Day	147.05	147.05	147.05	147.05	147.05
% of Summer Day	0.24%	0.13%	0.042%	−0.034%	−0.096%
Dayton Area					
2013	2014	2015	2016	2017	
Stage II Phase-out	0.310	0.201	0.110	0.034	−0.027
Low Permeation Hoses	−0.052	−0.052	−0.052	−0.052	−0.052
Daily Total	0.26	0.15	0.058	−0.018	−0.079
Typical Summer Day	99.66	99.66	99.66	99.66	99.66
% of Summer Day	0.26%	0.15%	0.058%	−0.018%	−0.079%

As illustrated in Table 1, and documented in Ohio's SIP revision, for each year prior to the widespread use of ORVR in Ohio (2017) starting in 2013, the VOC emissions increase associated with the removal of Stage II systems is eventually offset by the VOC emission reductions attributed to ORVR being in widespread use in Ohio and the requirement of low permeation hoses at GDFs.

EPA believes that the removal of the Ohio Stage II program does not interfere with Ohio's ability to demonstrate compliance with the 8-hour ozone NAAQS in all three areas. This is based on the use of permanent, enforceable, contemporaneous, surplus emissions reductions achieved through the requirement of low permeation hoses at GDFs, and the fact that the small emissions increase is both temporary and insignificant with respect to the total summer day emission rates for sectors in these areas.

EPA also examined whether the removal of Stage II program requirements in all three areas will interfere with attainment of other air quality standards. All the counties in the Dayton area are designated attainment for all standards, including sulfur dioxide and nitrogen dioxide. Cincinnati is designated attainment for all standards other than ozone and sulfur dioxide. The Cleveland area is designated attainment for all standards other than ozone, lead (Cuyahoga Co.), sulfur dioxide (Lake Co.) and particulate matter (Cuyahoga and Lorain Counties). Based on Ohio EPA's 110(l) analysis, EPA has no reason to believe that the removal of the Stage II program in Ohio will cause the areas to become nonattainment for any of these pollutants. In addition, EPA believes that removing the Stage II program requirements in Ohio will not interfere with the areas' ability to meet any other CAA requirement.

Based on the above discussion and the state's section 110(l) demonstration, EPA believes that removal of the Stage II program would not interfere with attainment or maintenance of any of the NAAQS in the Cleveland, Cincinnati, and Dayton areas and would not interfere with any other applicable requirement of the CAA, and thus, are approvable under CAA section 110(l).

IV. What action is EPA proposing to take?

EPA is proposing to approve the revision to the Ohio ozone SIP submitted by Ohio EPA on July 15, 2015, and February 26, 2016, because we find that the revision meets all applicable requirements and it would not interfere with reasonable further progress or attainment of any of the NAAQS.

V. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Ohio rule 3745–21–09 "Control of emissions of volatile organic compounds from stationary sources and perchloroethylene from dry cleaning facilities." effective January 17, 2014. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and/or at the EPA Region 5 Office (please contact the person identified in the "For Further Information Contact" section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Volatile organic compounds.

Dated: June 27, 2016.

Robert Kaplan,

Acting Regional Administrator, Region 5.

[FR Doc. 2016–15617 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0846; FRL–9948–39–Region 9]

Promulgation of Air Quality Implementation Plans; Arizona; Regional Haze Federal Implementation Plan; Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise provisions of the Arizona Regional Haze Federal Implementation Plan (FIP) applicable to the Phoenix Cement Company (PCC) Clarkdale Plant and the CalPortland Cement (CPC) Rillito Plant. In response to requests for reconsideration from the plants' owners, we propose to replace the control technology optimization requirements for nitrogen oxides (NO_X) applicable to Kiln 4 at the Clarkdale Plant and Kiln 4 at the Rillito Plant with a series of revised recordkeeping and reporting requirements. We are seeking comment on this proposed action.

DATES: Written comments must be submitted on or before August 15, 2016. Requests for a public hearing must be received on or before July 15, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2015–0846 at *http://www.regulations.gov,* or via email to *limaye.vijay@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Vijay Limaye, U.S. EPA, Region 9, Planning Office, Air Division, AIR–2, 75 Hawthorne Street, San Francisco, CA 94105. Vijay Limaye can be reached at telephone number (415) 972–3086 and via electronic mail at *limaye.vijay@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us," and "our" refer to the EPA.

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I. General Information

A. Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

- The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.
- The initials *ADEQ* mean or refer to the Arizona Department of Environmental Quality.
- The words *Arizona* and *State* mean the State of Arizona.
- The initials *BART* mean or refer to Best Available Retrofit Technology.

- The term *Class I area* refers to a mandatory Class I Federal area.[1]
- The initials *CBI* mean or refer to Confidential Business Information.
- The initials *CPC* mean or refer to CalPortland Cement.
- The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.
- The initials *FIP* mean or refer to Federal Implementation Plan.
- The initials NO_X mean or refer to nitrogen oxides.
- The initials *PCC* mean or refer to Phoenix Cement Company.
- The initials *SIP* mean or refer to State Implementation Plan.
- The initials *SNCR* mean or refer to selective non-catalytic reduction.
- The initials *SRPMIC* mean or refer to Salt River Pima-Maricopa Indian Community.

B. Docket

The proposed action relies on documents, information, and data that are listed in the index on *http://www.regulations.gov* under docket number EPA–R09–OAR–2015–0846. Although listed in the index, some information is not publicly available (*e.g.,* CBI). Certain other material, such as copyrighted material, is publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Planning Office of the Air Division, AIR–2, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 9–5:00 PDT, excluding Federal holidays.

C. Public Hearings

If anyone contacts the EPA by July 15, 2016 requesting to speak at a public hearing, the EPA will schedule a public hearing and announce the hearing in the **Federal Register**. Contact Vijay Limaye at (415) 972–3086 or at *limaye.vijay@epa.gov* to request a hearing or to determine if a hearing will be held.

II. Background

A. Summary of Statutory and Regulatory Requirements

This section provides a brief overview of the requirements of the Clean Air Act (CAA) and the EPA's Regional Haze Rule, as they apply to this particular action. Please refer to our previous rulemakings on the Arizona Regional Haze State Implementation Plan (SIP) for additional background regarding the visibility protection provisions of the CAA and the Regional Haze Rule.[2]

Congress created a program for protecting visibility in the nation's national parks and wilderness areas in section 169A of the 1977 Amendments to the CAA. This section of the CAA establishes as a national goal the "prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from man-made air pollution."[3] Specifically, section 169A(b)(2)(A) of the CAA requires states to revise their SIPs to contain such measures as may be necessary to make reasonable progress towards the natural visibility goal. In the 1990 CAA Amendments, Congress amended the visibility provisions in the CAA to focus attention on the problem of regional haze, which is visibility impairment produced by a multitude of sources and activities located across a broad geographic area.[4] We promulgated the Regional Haze Rule in 1999, which requires states to develop and implement SIPs to ensure reasonable progress toward improving visibility in mandatory Class I Federal areas[5] by reducing emissions that cause or contribute to regional haze.[6]

B. History of FIP Requirements

The Arizona Department of Environmental Quality (ADEQ) submitted a Regional Haze SIP to the EPA on February 28, 2011. The EPA promulgated two final rules approving in part and disapproving in part the Arizona Regional Haze SIP. The first final rule addressed the State's BART determinations for three power plants (Apache Generating Station, Cholla Power Plant, and Coronado Generating Station).[7] The second final rule, which addressed the remaining elements of the Arizona Regional Haze SIP, included our disapproval of the State's analysis of reasonable progress measures for point sources of NO_X.[8]

In a third final rule, the EPA promulgated a FIP addressing the requirements of the Regional Haze Rule and interstate visibility transport for the remainder of the disapproved portions of Arizona's Regional Haze SIP.[9] Among other things, the Arizona Regional Haze FIP includes requirements for NO_X emission controls applicable to PCC Clarkdale Plant Kiln 4 and CPC Rillito Plant Kiln 4 under the reasonable progress requirements of the Regional Haze Rule. In particular, the EPA established two alternative emission limits for NO_X on Kiln 4 of the Clarkdale Plant: A 2.12 lb/ton limit or an 810 tons/year limit. The lb/ton limit equates to the installation of SNCR, based on a 50 percent control efficiency, while the ton/year limit could be met either by installing SNCR or by maintaining recent production levels. We set an emission limit for NO_X at the Rillito Plant of 3.46 lb/ton, based on a 35 percent control efficiency. The FIP also includes monitoring, recordkeeping, and reporting requirements and a compliance deadline for the final NO_X emission limits of December 31, 2018. Finally, in response to comments alleging that SNCR control efficiencies of 50 percent for Kiln 4 at the Clarkdale Plant and 35 percent for Kiln 4 at the Rillito Plant were unsupported and that SNCR was capable of achieving higher control efficiencies, we included in the final FIP requirements for control technology demonstration ("optimization requirements") for the SNCR systems at both plants, which entail the collection of data that then could be used to determine if a higher control efficiency would be achievable.

C. Petitions for Reconsideration and Stay

PCC and CPC each submitted a petition to the EPA on November 3, 2014, seeking administrative reconsideration and a partial stay of the final FIP under CAA section 307(d)(7)(B) and the Administrative Procedure Act.[10] In their petitions, both companies raised multiple objections to the optimization requirements in the FIP. CPC asserted that the requirements were burdensome, expensive, and unnecessary, given that CPC had already

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[1] Although states and tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to "mandatory Class I Federal areas."

[2] 77 FR 42834, 42837–42839 (July 20, 2012), (Arizona Regional Haze "Phase 1" Rule) 77 FR 75704, 75709–75712 (December 21, 2012), (Arizona Regional Haze "Phase 2" Rule).

[3] 42 U.S.C. 7491(a)(1).

[4] See CAA section 169B, 42 U.S.C. 7492.

[5] Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas, and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). When we use the term "Class I area" in this action, we mean a "mandatory Class I Federal area."

[6] See generally 40 CFR 51.308.

[7] 77 FR 72512 (December 5, 2012).

[8] 78 FR 46142 (July 30, 2013).

[9] 79 FR 52420 (September 3, 2014) (Arizona Regional Haze "Phase 3" Rule).

[10] Letter from Verle C. Martz, PCC, to Regina McCarthy, EPA (November 3, 2014); Letter from Jay Grady, CPC, to Regina McCarthy, EPA (November 3, 2014).

"evaluated fuels, fuel fineness, and the other characteristics listed in the Optimization Protocol" as part of its effort to reduce energy usage.[11] PCC stated that the requirements "would be burdensome to implement" and "would substantially interfere with the cement manufacturing operations" at the Clarkdale Plant.[12] PCC further asserted that requirements would harm the Salt River Pima-Maricopa Indian Community (SRPMIC), which relies on revenue from the Clarkdale Plant.[13]

The EPA sent letters to PCC and CPC on January 16, 2015 and January 27, 2015, respectively, granting reconsideration of the optimization requirements pursuant to CAA section 307(d)(7)(B).[14] Today's notice of proposed rulemaking constitutes the EPA's proposed action on reconsideration.

III. Proposed FIP Revision for the PCC Clarkdale Plant and the CPC Rillito Plant

A. The EPA's Evaluation of Control Technology Demonstration Requirements

In light of the objections to the control technology demonstration requirements raised by CPC and PCC, we have re-evaluated the necessity of these requirements for the Rillito and Clarkdale plants. As explained in our September 3, 2014 final rule, the two objectives of the control technology demonstration requirements are to ensure that the NO_X emission limits for the cement kilns are appropriate and to ensure that performance of the SNCR systems at the kilns is optimized.[15] In developing this proposed action on reconsideration, we have considered whether it is possible to achieve these objectives through other means. In particular, we have identified additional information regarding SNCR performance and NO_X emission rates from SNCR-equipped cement kilns that supports the existing NO_X emission limits for the Rillito and Clarkdale kilns in the FIP. As a result, we no longer consider it necessary for PCC and CPC to adhere to the relatively detailed and prescriptive control technology demonstration requirements in the existing FIP. We are therefore proposing to remove the control technology demonstration requirements and are proposing a set of revised recordkeeping and reporting requirements that will require CPC and PCC to report information regarding SNCR system design and optimization in a less prescribed manner.

1. Rillito Plant Kiln 4

The EPA is proposing to remove the control technology demonstration requirements for Kiln 4 (the preheater/precalciner kiln) at the CPC Rillito Plant based on NO_X emission data from a similar kiln at another CPC facility, the Mojave Plant. On December 15, 2011, CPC entered into a consent decree with the EPA, which required the installation of SNCR on the single preheater/precalciner kiln at the Mojave Plant. As part of the consent decree, this preheater/precalciner kiln at the Mojave Plant was subject to certain control technology demonstration requirements. Commonly referred to as a "test and set" approach, these consent decree provisions required CPC to design and install an SNCR system, develop a protocol for optimizing its operation, record NO_X emission data over a long-term period, and propose a site-specific emission limit based on those results.

As noted in the response to comments in our September 3, 2014 final rule,[16] CPC submitted comments noting certain site-specific aspects of the Rillito Kiln 4 that indicated it could not achieve the same level of SNCR control efficiency as the Mojave Plant's kiln.[17] In our final rule, we indicated that we found this analysis of Rillito Kiln 4 to be generally reasonable, and based the final 3.46 lb/ton NO_X limit on the 35% SNCR control efficiency estimated by CPC. While preparing our final rule, we examined the data used to develop the Mojave Plant optimization protocol, which indicated that the SNCR system at the Mojave Plant could be expected to achieve in the range of 30–60% control efficiency. Given that this range included control efficiencies that were significantly higher than the efficiency on which the final limit for Rillito Kiln 4 was based, these initial data from Mojave suggested that inclusion of control technology demonstration requirements in the final rule would be appropriate in order to allow us to evaluate whether or not Rillito Kiln 4 could be further optimized to achieve a more stringent control efficiency.

Following promulgation of the final rule on September 3, 2014, the Mojave Plant completed a 270-day demonstration period of its SNCR system.[18] Based upon the consent decree methodology, the emission data from the demonstration period indicate a NO_X limit for the Mojave Plant kiln of 2.70 lb/ton on a rolling 30-kiln-operating-day basis. This is approximately equal to an SNCR control efficiency of 40%, which is on the lower end of the range that was suggested by the optimization protocol.[19]

Given that the SNCR system on the Rillito Kiln 4 can be expected to underperform the Mojave Plant, and that the Mojave demonstration period data resulted in a limit reflecting an SNCR control efficiency of only 40%,[20] we find that the final NO_X limit for Rillito Kiln 4, which is based on a 35% control efficiency, is adequately supported by the available data. Accordingly, we no longer consider it necessary for CPC to meet the relatively detailed and prescriptive control technology demonstration requirements in the existing FIP. We are therefore proposing to remove the control technology demonstration requirements from the FIP. As explained in section III.B below, we are proposing to replace the control technology demonstration requirements with a set of revised recordkeeping and reporting requirements that will require CPC to report similar information regarding SNCR system design and optimization, but in a less prescribed manner.

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[11] Letter from Jay Grady, CPC, to Regina McCarthy, EPA (November 3, 2014), attachment entitled "Petition of CalPortland Company for Partial Reconsideration and Request for Administrative Stay of EPA Final Rule, Promulgation of Air Quality Implementation Plans; Arizona; Regional Haze and Interstate Visibility Transport Federal Implementation Plan Published at 79 FR 52420" at 4.

[12] Letter from Verle C. Martz, PCC, to Regina McCarthy, EPA (November 3, 2014) at 2.

[13] We note that while the Clarkdale Plant is tribally owned, it is not located on tribal land. It is subject to State jurisdiction and is regulated by ADEQ.

[14] Letter from Jared Blumenfeld, EPA, to Verle C. Martz, PCC (January 16, 2015); Letter from Jared Blumenfeld, EPA, to Jay Grady, CPC (January 27, 2015).

[15] See 79 FR 52455–52456, 52462.

[16] 79 FR 52462–52463.

[17] Letter from Jay Grady, CPC, to Thomas Webb, EPA (March 31, 2014) and Exhibit 1, "Evaluation of EPA's Reasonable Progress Analysis for Kiln 4 at CalPortland Company's Rillito Cement Plant." To summarize, CPC asserted that an SNCR system on Rillito Kiln 4 would operate with less efficient exhaust mixing, lower ammonia injection temperatures, and lower oxygen concentrations, all of which would reduce SNCR effectiveness.

[18] The demonstration period extended from February to November 2014, and was submitted to the EPA in early 2015. See spreadsheet "Mojave Demonstration Period Data.xlsx."

[19] Based on a baseline pre-SNCR NO_X emission rate of 4.5 lb/ton. This value was based on the highest of recent source test results, as summarized in spreadsheet "CPC annual revised emissions chart.xlsx"

[20] We note that the difference between the two limits, 2.70 lb/ton and 3.46 lb/ton, is larger than what would be suggested by a mere 5% difference in control efficiencies (*i.e.*, between 40% and 35%). This is primarily due to the different baseline emission rates of the two kilns, with the Rillito kiln having a much higher baseline NO_X emission rate than Mojave, in addition to a lower SNCR effectiveness.

2. Clarkdale Plant Kiln 4

The EPA is also proposing to remove the control technology demonstration requirements for Kiln 4 (the preheater/precalciner kiln) at the PCC Clarkdale Plant based on the NO_X emission data from the preheater/precalciner kiln at the CPC Mojave Plant. In the case of Clarkdale Kiln 4, the relatively recent construction of the kiln[21] and its generally lower pre-control NO_X emission rates[22] indicate that an SNCR system on Clarkdale Kiln 4 would be able to achieve a lower NO_X emission limit than the Mojave Plant. The final NO_X limit promulgated for Clarkdale Kiln 4 is 2.12 lb/ton, on a rolling 30-kiln-operating-day basis, which is based on a 50% control efficiency. As noted in the previous section, the emission data from the Mojave Plant demonstration period indicated a final NO_X limit of 2.70 lb/ton on a rolling 30 kiln operating day basis, which corresponds to an SNCR control efficiency of approximately 40%. Given that a more stringent emission limit and SNCR control efficiency was not demonstrated at the Mojave Plant, we consider the final limit for Clarkdale Kiln 4 to be sufficiently stringent and supported by the available data. Accordingly, we no longer consider it necessary for PCC to adhere to the relatively detailed and prescriptive control technology demonstration requirements in the existing FIP. We are therefore proposing to remove the control technology demonstration requirements. As explained in section III.B below, we are proposing to replace the control technology demonstration requirements with a set of revised recordkeeping and reporting requirements that will require PCC to report similar information regarding SNCR system design and optimization, but in a less prescribed manner.

B. Revised Recordkeeping and Reporting Requirements

As described in III.A above, we no longer consider it necessary for CPC and PCC to comply with the relatively prescriptive and detailed optimization requirements established in our September 4, 2014 final rule. We are therefore proposing to remove the control technology demonstration requirements in the FIP for the Clarkdale and Rillito Plants, and instead are proposing certain revisions to the reporting and recordkeeping requirements that involve documentation and submittal of certain design and optimization activities that are part of a typical SNCR system installation. Specifically, we propose to require PCC and CPC to submit a report of SNCR design prior to commencing construction of the ammonia injection system at Clarkdale Kiln 4 and Rillito Kiln 4 respectively, including information regarding reagent type, locations selected for reagent injection, reagent injection rate, equipment arrangement, and kiln characteristics. In addition, PCC and CPC would be required to submit a report of SNCR debugging and process improvement activities, including a description of each process adjustment performed on the SNCR system, a discussion of whether the adjustment affected the NO_X emission rate, a description of the range over which the adjustment was examined, and a discussion of how the adjustment will be reflected or accounted for in kiln operating practices. PCC and CPC would also be required to submit any CEMS data and kiln operating data collected during the debugging and process improvement activities. These proposed revisions are detailed in the proposed regulatory text at 40 CFR 52.145(k).

C. Non-Interference With Applicable Requirements

The CAA requires that any revision to an implementation plan shall not be approved by the Administrator if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable requirement of the CAA.[23] Today's proposed revisions to the Arizona Regional Haze FIP would not affect any applicable requirements of the CAA because they would not alter the amount or timing of emission reductions from the Clarkdale Plant or the Rillito Plant. In particular, the proposed replacement of the control technology demonstration requirements with a series of recordkeeping and reporting requirements would not alter any of the applicable emission limitations, compliance determination methodologies, or compliance deadlines. Therefore, we propose to find that these revisions would comply with CAA section 110(l).

IV. The EPA's Proposed Action

For the reasons described above, the EPA proposes to revise the Arizona Regional Haze FIP to replace the control technology optimization requirements at the PCC Clarkdale Plant and the CPC Rillito Plant with a series of recordkeeping and reporting requirements. Please note that while the proposed regulatory text includes the entirety of 40 CFR 52.145(k), we are only proposing to revise those elements of the regulation related to optimization requirements.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed action is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). This proposed rule applies to only one facility and is therefore not a rule of general applicability.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Pursuant to 13 CFR 121.201, footnote 1, a firm is small if it is in NAICS 327310 (cement manufacturing) and the concern and its affiliates have no more than 750 employees. CPC is owned by Taiheiyo Cement Corporation, which has more than 750 employees.[24] PCC is a division of SRPMIC.[25] For the purposes of the RFA, tribal governments are not considered small governments. 5 U.S.C. 601(5). Therefore SRPMIC is not a small entity.

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[21] Clarkdale Kiln 4 was constructed in 2002. The Mojave preheater/precalciner kiln was constructed in 1981.

[22] For purposes of the reasonable progress determination, Clarkdale Kiln 4 has a baseline NO_X emission rate of 3.25 lb/ton. The Mojave baseline emission rate was 4.50 lb/ton.

[23] CAA Section 110(l), 42 U.S.C. 7410(l).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538. This action may significantly or uniquely affect small governments. As a tribal government, SRPMIC is considered a "small government" under UMRA. See 2 U.S.C. 658(11) and (13). The EPA consulted with SRPMIC concerning the regulatory requirements that might significantly or uniquely affect it.[26]

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or in the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. This proposed action, if finalized, would eliminate the SNCR optimization requirements that currently apply to the PCC Clarkdale Plant. The profits from the Clarkdale Plant are used to provide government services to SRPMIC's members.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development.[27]

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not change the level of environmental protection for any affected populations.

K. Determination Under Section 307(d)

Pursuant to CAA section 307(d)(1)(B), the EPA proposes to determine that this action is subject to the provisions of section 307(d). Section 307(d) establishes procedural requirements specific to certain rulemaking actions under the CAA. Pursuant to CAA section 307(d)(1)(B), the revision of the provisions of the Arizona Regional Haze FIP that apply to the PCC Clarkdale Plant and the CPC Rillito Plant is subject to the requirements of CAA section 307(d), as it constitutes a revision to a FIP under CAA section 110(c).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen oxides, Reporting and recordkeeping requirements, Visibility.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 15, 2016.

Alexis Strauss,

Acting Regional Administrator, EPA Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart D—Arizona

■ 2. Amend § 52.145 by:

■ a. Revising paragraph (k); and

■ b. Removing "Appendix A to § 52.145—Cement Kiln Control Technology Demonstration Requirements".

The revision reads as follows:

§ 52.145 Visibility protection.

* * * * *

(k) *Source-specific federal implementation plan for regional haze at Clarkdale Cement Plant and Rillito Cement Plant*—(1) *Applicability.* This paragraph (k) applies to each owner/operator of the following cement kilns in the state of Arizona: Kiln 4 located at the cement plant in Clarkdale, Arizona, and kiln 4 located at the cement plant in Rillito, Arizona.

(2) *Definitions.* Terms not defined in this paragraph (k)(2) shall have the meaning given them in the Clean Air Act or EPA's regulations implementing the Clean Air Act. For purposes of this paragraph (k):

Ammonia injection shall include any of the following: Anhydrous ammonia, aqueous ammonia or urea injection.

Continuous emission monitoring system or CEMS means the equipment required by this section to sample, analyze, measure, and provide, by means of readings recorded at least once every 15 minutes (using an automated data acquisition and handling system (DAHS)), a permanent record of NO_X emissions, diluent, or stack gas volumetric flow rate.

Kiln operating day means a 24-hour period between 12 midnight and the following midnight during which the kiln operates at any time.

Kiln operation means any period when any raw materials are fed into the kiln or any period when any combustion is occurring or fuel is being fired in the kiln.

NO_X means nitrogen oxides.

Owner/operator means any person who owns or who operates, controls, or supervises a cement kiln identified in paragraph (k)(1) of this section.

Unit means a cement kiln identified in paragraph (k)(1) of this section.

(3) *Emissions limitations.* (i) The owner/operator of kiln 4 of the Clarkdale Plant, as identified in paragraph (k)(1) of this section, shall not

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[24] See Taiheiyo Cement Corp. Annual Report 2015, pages 1 and 36.

[25] Letter from Diane Enos, President, SRPMIC, to Jared Blumenfield, Regional Administrator, EPA Region 9 (December 20, 2012).

[26] *See* Summary of Consultation with SRPMIC Regarding Regional Haze FIP Reconsideration.

[27] *Id.*

emit or cause to be emitted from kiln 4 NO_X in excess of 2.12 pounds of NO_X per ton of clinker produced, based on a rolling 30-kiln operating day basis.

(ii) The owner/operator of kiln 4 of the Rillito Plant, as identified in paragraph (k)(1) of this section, shall not emit or cause to be emitted from kiln 4 NO_X in excess of 3.46 pounds of NO_X per ton of clinker produced, based on a rolling 30-kiln operating day basis.

(4) *Alternative emissions limitation.* In lieu of the emission limitation listed in paragraph (k)(3)(i) of this section, the owner/operator of kiln 4 of the Clarkdale Plant may choose to comply with the following limitation by providing notification per paragraph (k)(13)(iv) of this section. The owner/operator of kiln 4 of the Clarkdale Plant, as identified in paragraph (k)(1) of this section, shall not emit or cause to be emitted from kiln 4 NO_X in excess of 810 tons per year, based on a rolling 12 month basis.

(5) *Compliance date.* (i) The owner/operator of each unit identified in paragraph (k)(1) of this section shall comply with the NO_X emissions limitations and other NO_X-related requirements of this paragraph (k)(3) of this section no later than December 31, 2018.

(ii) If the owner/operator of the Clarkdale Plant chooses to comply with the emission limit of paragraph (k)(4) of this section in lieu of paragraph (k)(3)(i) of this section, the owner/operator shall comply with the NO_X emissions limitations and other NO_X-related requirements of paragraph (k)(4) of this section no later than December 31, 2018.

(6) [Reserved]

(7) *Compliance determination*—(i) *Continuous emission monitoring system.* (A) At all times after the compliance date specified in paragraph (k)(5) of this section, the owner/operator of the unit at the Clarkdale Plant shall maintain, calibrate, and operate a CEMS, in full compliance with the requirements found at 40 CFR 60.63(f) and (g), to accurately measure concentration by volume of NO_X, diluent, and stack gas volumetric flow rate from the in-line/raw mill stack, as well as the stack gas volumetric flow rate from the coal mill stack. The CEMS shall be used by the owner/operator to determine compliance with the emission limitation in paragraph (k)(3) of this section, in combination with data on actual clinker production. The owner/operator must operate the monitoring system and collect data at all required intervals at all times the affected unit is operating, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, and required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments).

(B) At all times after the compliance date specified in paragraph (k)(5) of this section, the owner/operator of the unit at the Rillito Plant shall maintain, calibrate, and operate a CEMS, in full compliance with the requirements found at 40 CFR 60.63(f) and (g), to accurately measure concentration by volume of NO_X, diluent, and stack gas volumetric flow rate from the unit. The CEMS shall be used by the owner/operator to determine compliance with the emission limitation in paragraph (k)(3) of this section, in combination with data on actual clinker production. The owner/operator must operate the monitoring system and collect data at all required intervals at all times the affected unit is operating, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, and required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments).

(ii) *Methods.* (A) The owner/operator of each unit shall record the daily clinker production rates.

(B)(*1*) The owner/operator of each unit shall calculate and record the 30-kiln operating day average emission rate of NO_X, in lb/ton of clinker produced, as the total of all hourly emissions data for the cement kiln in the preceding 30-kiln operating days, divided by the total tons of clinker produced in that kiln during the same 30-day operating period, using the following equation:

$$E_D = k\frac{1}{(n)}\sum_{i=1}^{n}\frac{C_i Q_i}{P_i}$$

Where:

E[D] = 30 kiln operating day average emission rate of NO_X, lb/ton of clinker;
C[i] = Concentration of NO_X for hour i, ppm;
Q[i] = volumetric flow rate of effluent gas for hour i, where C[i] and Q[i] are on the same basis (either wet or dry), scf/hr; Clarkdale?
P[i] = total kiln clinker produced during production hour i, ton/hr;
k = conversion factor, 1.194 x 10<-7> for NO_X; and
n = number of kiln operating hours over 30 kiln operating days, n = 1 up to 720.

(*2*) For each kiln operating hour for which the owner/operator does not have at least one valid 15-minute CEMS data value, the owner/operator must use the average emissions rate (lb/hr) from the most recent previous hour for which valid data are available. Hourly clinker production shall be determined by the owner/operator in accordance with the requirements found at 40 CFR 60.63(b).

(C) At the end of each kiln operating day, the owner/operator shall calculate and record a new 30-day rolling average emission rate in lb/ton clinker from the arithmetic average of all valid hourly emission rates for the current kiln operating day and the previous 29 successive kiln operating days.

(D) Upon and after the completion of installation of ammonia injection on a unit, the owner/operator shall install, and thereafter maintain and operate, instrumentation to continuously monitor and record levels of ammonia injection for that unit.

(8) *Alternative compliance determination.* If the owner/operator of the Clarkdale Plant chooses to comply with the emission limits of paragraph (k)(4) of this section, this paragraph may be used in lieu of paragraph (k)(7) of this section to demonstrate compliance with the emission limits in paragraph (k)(4) of this section.

(i) *Continuous emission monitoring system.* At all times after the compliance date specified in paragraph (k)(5) of this section, the owner/operator of the unit at the Clarkdale Plant shall maintain, calibrate, and operate a CEMS, in full compliance with the requirements found at 40 CFR 60.63(f) and (g), to accurately measure concentration by volume of NO_X, diluent, and stack gas volumetric flow rate from the in-line/raw mill stack, as well as the stack gas volumetric flow rate from the coal mill stack. The CEMS shall be used by the owner/operator to determine compliance with the emission limitation in paragraph (k)(3) of this section, in combination with data on actual clinker production. The owner/operator must operate the monitoring system and collect data at all required intervals at all times the affected unit is operating, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, and required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments).

(ii) *Method.* Compliance with the ton per year NO_X emission limit described in paragraph (k)(4) of this section shall be determined based on a rolling 12 month basis. The rolling 12-month NO_X emission rate for the kiln shall be calculated within 30 days following the end of each calendar month in accordance with the following procedure: Step one, sum the hourly pounds of NO_X emitted for the month just completed and the eleven (11) months preceding the month just completed, to calculate the total pounds of NO_X emitted over the most recent twelve (12) month period for that kiln; Step two, divide the total pounds of NO_X calculated from Step one by two thousand (2,000) to calculate the total tons of NO_X. Each rolling 12-month NO_X emission rate shall include all emissions that occur during all periods within the 12-month period, including emissions from startup, shutdown and malfunction.

(iii) Upon and after the completion of installation of ammonia injection on the unit, the owner/operator shall install, and thereafter maintain and operate, instrumentation to continuously monitor and record levels of ammonia injection for that unit.

(9) *Recordkeeping.* The owner/operator of each unit shall maintain the following records for at least five years:

(i) All CEMS data, including the date, place, and time of sampling or measurement; emissions and parameters sampled or measured; and results.

(ii) All records of clinker production.

(iii) Daily 30-day rolling emission rates of NO_X, calculated in accordance with paragraph (k)(7)(ii) of this section.

(iv) Records of quality assurance and quality control activities for emissions measuring systems including, but not limited to, any records specified by 40 CFR part 60, Appendix F, Procedure 1.

(v) Records of ammonia consumption, as recorded by the instrumentation required in paragraph (k)(7)(ii)(D) of this section.

(vi) Records of all major maintenance activities conducted on emission units, air pollution control equipment, CEMS and clinker production measurement devices.

(vii) Any other records specified by 40 CFR part 60, subpart F, or 40 CFR part 60, Appendix F, Procedure 1.

(10) *Alternative recordkeeping requirements.* If the owner/operator of the Clarkdale Plant chooses to comply with the emission limits of paragraph (k)(4) of this section, the owner/operator shall maintain the records listed in this paragraph in lieu of the records contained in paragraph (k)(9) of this section. The owner or operator shall maintain the following records for at least five years:

(i) All CEMS data, including the date, place, and time of sampling or measurement; emissions and parameters sampled or measured; and results.

(ii) Monthly rolling 12-month emission rates of NO_X, calculated in accordance with paragraph (k)(8)(ii) of this section.

(iii) Records of quality assurance and quality control activities for emissions measuring systems including, but not limited to, any records specified by 40 CFR part 60, Appendix F, Procedure 1.

(iv) Records of ammonia consumption, as recorded by the instrumentation required in paragraph (k)(8)(iii) of this section.

(v) Records of all major maintenance activities conducted on emission units, air pollution control equipment, and CEMS measurement devices.

(vi) Any other records specified by 40 CFR part 60, subpart F, or 40 CFR part 60, Appendix F, Procedure 1.

(11) *Reporting.* All reports and notifications required under this paragraph (k) shall be submitted by the owner/operator to U.S. Environmental Protection Agency, Region 9, Enforcement Division via electronic mail to *aeo_r9@epa.gov* and to Air Division via electronic mail to *R9AirPermits@epa.gov*. Reports required under this paragraph (k)(11)(iii) through (k)(11)(vii) of this section shall be submitted within 30 days after the applicable compliance date in paragraph (k)(5) of this section and at least semiannually thereafter, within 30 days after the end of a semiannual period. The owner/operator may submit reports more frequently than semiannually for the purposes of synchronizing reports required under this section with other reporting requirements, such as the title V monitoring report required by 40 CFR 70.6(a)(3)(iii)(A), but at no point shall the duration of a semiannual period exceed six months.

(i) Prior to commencing construction of the ammonia injection system, the owner/operator shall submit to EPA a report describing the design of the SNCR system. This report shall include: Reagent type, description of the locations selected for reagent injection, reagent injection rate (expressed as a molar ratio of reagent to exhaust gas), equipment list, equipment arrangement, and a summary of kiln characteristics that were relied upon as the design basis for the SNCR system.

(ii) Within 30 days following the NO_X compliance date in paragraph (k)(5)(i) of this section, the owner/operator shall submit to EPA a report of any process improvement or debugging activities that were performed on the SNCR system. This report shall include: A description of each process adjustment performed on the SNCR system or the kiln, a discussion of whether the adjustment affected NO_X emission rates, a description of the range (if applicable) over which the adjustment was examined, and a discussion of how the adjustment will be reflected or account for in kiln operating practices. If CEMS data or kiln operating data were recorded during process improvement or debugging activities, the owner/operator shall submit the recorded CEMS and kiln operating data with the report. The data shall be submitted in an electronic format consistent with and able to be manipulated by a spreadsheet program such as Microsoft Excel.

(iii) The owner/operator shall submit a report that lists the daily 30-day rolling emission rates for NO_X.

(iv) The owner/operator shall submit excess emissions reports for NO_X limits. Excess emissions means emissions that exceed the emissions limits specified in paragraph (k)(3) of this section. The reports shall include the magnitude, date(s), and duration of each period of excess emissions, specific identification of each period of excess emissions that occurs during startups, shutdowns, and malfunctions of the unit, the nature and cause of any malfunction (if known), and the corrective action taken or preventative measures adopted.

(v) The owner/operator shall submit CEMS performance reports, to include dates and duration of each period during which the CEMS was inoperative (except for zero and span adjustments and calibration checks), reason(s) why the CEMS was inoperative and steps taken to prevent recurrence, and any CEMS repairs or adjustments.

(vi) The owner/operator shall also submit results of any CEMS performance tests specified by 40 CFR part 60, Appendix F, Procedure 1 (Relative Accuracy Test Audits, Relative Accuracy Audits, and Cylinder Gas Audits).

(vii) When no excess emissions have occurred or the CEMS has not been inoperative, repaired, or adjusted during the reporting period, the owner/operator shall state such information in the reports required by paragraph (k)(9)(ii) of this section.

(12) *Alternative reporting requirements.* If the owner/operator of the Clarkdale Plant chooses to comply with the emission limits of paragraph (k)(4) of this section, the owner/operator shall submit the reports listed in this paragraph in lieu of the reports contained in paragraph (k)(11) of this section. All reports required under this paragraph (k)(12) shall be submitted within 30 days after the applicable compliance date in paragraph (k)(5) of this section and at least semiannually thereafter, within 30 days after the end of a semiannual period. The owner/operator may submit reports more frequently than semiannually for the purposes of synchronizing reports

required under this section with other reporting requirements, such as the title V monitoring report required by 40 CFR 70.6(a)(3)(iii)(A), but at no point shall the duration of a semiannual period exceed six months.

(i) The owner/operator shall submit a report that lists the monthly rolling 12-month emission rates for NO_X.

(ii) The owner/operator shall submit excess emissions reports for NO_X limits. Excess emissions means emissions that exceed the emissions limits specified in paragraph (k)(3) of this section. The reports shall include the magnitude, date(s), and duration of each period of excess emissions, specific identification of each period of excess emissions that occurs during startups, shutdowns, and malfunctions of the unit, the nature and cause of any malfunction (if known), and the corrective action taken or preventative measures adopted.

(iii) The owner/operator shall submit CEMS performance reports, to include dates and duration of each period during which the CEMS was inoperative (except for zero and span adjustments and calibration checks), reason(s) why the CEMS was inoperative and steps taken to prevent recurrence, and any CEMS repairs or adjustments.

(iv) The owner/operator shall also submit results of any CEMS performance tests specified by 40 CFR part 60, Appendix F, Procedure 1 (Relative Accuracy Test Audits, Relative Accuracy Audits, and Cylinder Gas Audits).

(v) When no excess emissions have occurred or the CEMS has not been inoperative, repaired, or adjusted during the reporting period, the owner/operator shall state such information in the reports required by paragraph (k)(9)(ii) of this section.

(13) *Notifications.* (i) The owner/operator shall submit notification of commencement of construction of any equipment which is being constructed to comply with the NO_X emission limits in paragraph (k)(3) of this section.

(ii) The owner/operator shall submit semiannual progress reports on construction of any such equipment.

(iii) The owner/operator shall submit notification of initial startup of any such equipment.

(iv) By June 30, 2018, the owner/operator of the Clarkdale Plant shall notify EPA Region 9 by letter whether it will comply with the emission limits in paragraph (k)(3)(i) of this section or whether it will comply with the emission limits in paragraph (k)(4) of this section. In the event that the owner/operator does not submit timely and proper notification by June 30, 2018, the owner/operator of the Clarkdale Plant may not choose to comply with the alternative emission limits in paragraph (k)(4) of this section and shall comply with the emission limits in paragraph (k)(3)(i) of this section.

(14) *Equipment operation.* (i) At all times, including periods of startup, shutdown, and malfunction, the owner or operator shall, to the extent practicable, maintain and operate the unit including associated air pollution control equipment in a manner consistent with good air pollution control practices for minimizing emissions. Pollution control equipment shall be designed and capable of operating properly to minimize emissions during all expected operating conditions. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Regional Administrator which may include, but is not limited to, monitoring results, review of operating and maintenance procedures, and inspection of the unit.

(ii) After completion of installation of ammonia injection on a unit, the owner or operator shall inject sufficient ammonia to achieve compliance with NO_X emission limits set forth in paragraph (k)(3) of this section for that unit while preventing excessive ammonia emissions.

(15) *Enforcement.* Notwithstanding any other provision in this implementation plan, any credible evidence or information relevant as to whether the unit would have been in compliance with applicable requirements if the appropriate performance or compliance test had been performed, can be used to establish whether or not the owner or operator has violated or is in violation of any standard or applicable emission limit in the plan.

[FR Doc. 2016–15305 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 232

[Docket DARS–2016–0009]

RIN 0750–AI90

Defense Federal Acquisition Regulation Supplement: Contract Financing (DFARS Case 2015–D026)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) regarding the use of customary contract financing, other than loan guarantees and advance payments, on certain fixed-price contracts.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before August 29, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2015–D026, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "DFARS Case 2015–D026" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "DFARS Case 2015–D026." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "DFARS Case 2015–D026" on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2015–D026 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Mr. Mark Gomersall, OUSD (AT&L) DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Mark Gomersall, telephone 571–372–6099.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS regarding the use of customary contract financing, other than loan guarantees and advance payments identified in FAR part 32, on fixed-price contracts with a period of performance in excess of one year that meet the dollar thresholds established in FAR 32.104(d). DoD has determined that the use of such customary contract financing provides improved cash flow as an incentive for commercial companies to do business with DoD, is in DoD's best interest, and requires no further justification of its use.

II. Discussion and Analysis

The proposed rule amends DFARS 232.104 to state that DoD has made the determination that the use of customary contract financing (see FAR 32.113), other than loan guarantees and advance payments, is in DoD's best interest, and further justification of its use is unnecessary on fixed-price contracts that meet the dollar thresholds established in FAR 32.104(d), with a period of performance in excess of a year, and in solicitations expected to result in such contracts.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to state that DoD has made the determination that the use of customary contract financing (see Federal Acquisition Regulation (FAR) 32.113), other than loan guarantees and advance payments, is in DoD's best interest, and further justification of its use is unnecessary on fixed-price contracts that meet the dollar thresholds established in FAR 32.104(d), with a period of performance in excess of a year, and in solicitations expected to result in such contracts.

The objective of the proposed rule is to clarify that the use of certain customary contract financing does not require further justification, as it has been determined to be in DoD's best interest, and the use of the specified contract financing is an incentive for commercial companies to do business with DoD.

This rule will apply to DoD contractors, including small entities, where a fixed-price contract with a period of performance in excess of one year and meeting the thresholds in FAR 32.104(d) is contemplated.

There is no change to reporting or recordkeeping as a result of this rule. This rule changes processes that are internal to the Government and does not have any impact on small entities for reporting or recordkeeping.

The rule does not duplicate, overlap, or conflict with any other Federal rules. There are no known significant alternative approaches to the rule that would meet the requirements.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2015–D026), in correspondence.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 232

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 232 is proposed to be amended as follows:

PART 232—CONTRACT FINANCING

■ 1. The authority citation for part 232 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Add section 232.104 to subpart 232.1 to read as follows:

232.104 Providing contract financing.

For fixed-price contracts with a period of performance in excess of a year that meet the dollar thresholds established in FAR 32.104(d), and for solicitations expected to result in such contracts, in lieu of the requirement at FAR 32.104(d)(1)(ii) for the contractor to demonstrate actual financial need or the unavailability of private financing, DoD has determined that—

(1) The use of customary contract financing (see FAR 32.113), other than loan guarantees and advance payments, is in DoD's best interest; and

(2) Further justification of its use in individual acquisitions is unnecessary.

[FR Doc. 2016–15246 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2016–0020]

RIN 0750–AI96

Defense Federal Acquisition Regulation Supplement: Administrative Cost To Issue and Administer a Contract (DFARS Case 2016–D020)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to revise the estimated administrative cost to award and administer a contract, for the purpose of evaluating bids for multiple awards.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before August 29, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D020, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "DFARS Case 2016–D020" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "DFARS Case 2016–D020." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "DFARS Case 2016–D020" on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D020 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Mr. Christopher Stiller, OUSD (AT&L) DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement a policy that addresses the Government's cost to award and administer a contract, for the purpose of evaluating bids for multiple awards. The provision at DFARS 252.247–7008, Evaluation of Bids—Basic, and its Alternate I, reflects that $500 is the administrative cost to the Government for issuing and administering contracts. Based on increase in the Consumer Price Index since 1990, an upward adjustment of $500 in the provision to $1,000 would be a realistic reflection of the actual cost to the Government to issue and administer a contract. This increase conforms to an equivalent adjustment proposed under FAR Case 2016–003 published in the **Federal Register** on May 12, 2016 (81 FR 29514).

II. Discussion and Analysis

Amendments to DFARS provision 252.247–7008, Evaluation of Bids—Basic, and its Alternate I, are proposed by this rule. A monetary adjustment is proposed to increase, from $500 to $1,000, the administrative cost to the Government for issuing and administering each contract to be awarded under a solicitation for the purpose of evaluating bids for multiple awards.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

The clause at DFARS 252.247–7008, Evaluation of Bids, reflects that $500 is the administrative cost to the Government for issuing and administering contracts. The rule is necessary to reestablish a more realistic estimate of the cost to award and administer a contract, for the purpose of evaluating bids for multiple awards. The estimated administrative cost to award and administer a contract has not changed since 1990.

The objective of this rule is to revise DFARS 252.247–7008, Evaluation of Bids, to include an inflation adjustment based on increase in the Consumer Price Index since 1990. See *http://data.bls.gov/cgi-bin/cpicalc.pldata.* The adjustment will change the estimated cost to award and administer a contract from $500 to $1,000.

According to the Federal Procurement Data System, in fiscal year 2015, the Federal Government made approximately 2,019 definitive contract awards to small businesses using sealed bidding procedures and 103 indefinite delivery contract awards to small businesses using sealed bidding procedures, 12 of which were multiple awards. Thus, DoD does not expect this rule to have an economic impact on a substantial number of small entities. Additionally, the rule does not place any new requirements on small entities.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no significant alternatives to the rule which accomplish the stated objectives.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2016–D020), in correspondence.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is proposed to be amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

252.247–7009 [Amended]

■ 2. Amend section 252.247–7008 by—
■ a. Removing the provision date "(APR 2014)" and adding "(DATE)" in its place;
■ b. In paragraph (b)(1), removing "$500" and adding "$1,000" in its place; and
■ c. In Alternate I:
■ i. Removing the clause date "(APR 2014)" and adding "(DATE)" in its place; and
■ ii. In paragraph (b)(1), removing "$500" and adding "$1,000" in its place.

[FR Doc. 2016–15257 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 176, 178, and 180

[Docket No. PHMSA–2015–0102 (HM–219A)]

RIN 2137–AF09

Hazardous Materials: Miscellaneous Petitions for Rulemaking (RRR)

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: In response to petitions for rulemaking submitted by the regulated community, PHMSA proposes to amend the Hazardous Materials Regulations (HMR; 49 CFR parts 171 through 180) to update, clarify, or provide relief from miscellaneous regulatory requirements. Specifically, PHMSA is proposing amendments that include, but are not

limited to, the following: Incorporating by Reference (IBR) multiple publications from both the Compressed Gas Association (CGA) and the Chlorine Institute; addressing inconsistencies with domestic and international labels and placards; permitting alternative testing for aerosols; no longer mandating that excepted quantities comply with the emergency response telephone requirement; allowing electronic signatures for Environmental Protection Agency (EPA) manifest forms; and no longer requiring the service pressure to be marked on Department of Transportation (DOT) 8 and 8L cylinders.

DATES: Comments must be submitted by August 29, 2016. To the extent possible, PHMSA will consider late-filed comments as a final rule is developed.

ADDRESSES: You may submit comments by identification of the docket number [PHMSA–2015–0102 (HM–219A)] by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Dockets Management System; U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* To U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number for this notice at the beginning of the comment. All comments received will be posted without change to the Federal Docket Management System (FDMS), including any personal information.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**). To access and review The Chlorine Institute publications (1) Chlorine Institute Emergency Kit "A" for 100-lb. & 150-lb. Chlorine Cylinders, Edition 12, Revision 2, July 2014 go to *https://bookstore.chlorineinstitute.org/iba-instruction-booklet-chlorine-institute-emergency-kit-a-for-100-lb-and-150-lb-chlorine-cylinders-166.html;* (2) Chlorine Institute Emergency Kit "B" for Chlorine Ton Containers, Edition 11, Revision 1, July 2014 go to *https://bookstore.chlorineinstitute.org/mm5/merchant.mvc?Session_ID=832f559635b70c753d7a6780f4876094&Store_Code=ci2store&Screen=PROD&Product_Code=EPR_IB_B–HC&;* (3) Pamphlet 57, Emergency Shut-Off Systems for Bulk Transfer of Chlorine, Edition 6, June 2015 go to *https://bookstore.chlorineinstitute.org/mm5/merchant.mvc?Session_ID=832f559635b70c753d7a6780f4876094&Store_Code=ci2store&Screen=PROD&Product_Code=SPHP0057–HC&;* and (4) Pamphlet 168, Guidelines for Dual Valve Systems for Bulk Chlorine Transport, Edition 2, July 2015 go to *https://bookstore.chlorineinstitute.org/mm5/merchant.mvc?Session_ID=832f559635b70c753d7a6780f4876094&Store_Code=ci2store&Screen=PROD&Product_Code=SPHP0168–HC&.* To access and review DoD publications include the following: (1) TB 700–2; NAVSEAINST 8020.8C; TO 11A–1–47: DoD Ammunition and Explosives Hazard Classification Procedures, 30 July 2012, go to *https://www.ddesb.pentagon.mil/documents/?pg=subcont-internationalissuances;* and (2) DLAR 4145.41/AR 700–143/NAVSUPINST 4030.55D/AFMAN 24–210_IP/MCO 4030.40C: Packaging of Hazardous Materials, 21 April 2015 go to *http://www.dla.mil/Portals/104/Documents/J5StrategicPlansPolicy/PublicIssuances/r4145.41.pdf*. To access and review Compressed Gas Association (CGA) publications including "CGA C–7–2014: Guide to Classification and Labeling of Compressed Gases, Tenth Edition" and "CGA V–9, 2012, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, Seventh Edition" go to *https://www.cganet.com/customer/dot.aspx.*

FOR FURTHER INFORMATION CONTACT: Steven Andrews or Matthew Nickels, (202) 366–8553, Office of Hazardous Materials Standards, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

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I. Background

The Administrative Procedure Act (APA) requires Federal agencies to give interested persons the right to petition an agency to issue, amend, or repeal a rule (5 U.S.C. 553(e)). Section 106.95 of the HMR contains the rulemaking procedures for persons to ask PHMSA (also "we" or "us") to add, amend, or delete a regulation by filing a petition for rulemaking containing adequate support for the requested action. In this NPRM, PHMSA proposes to amend the HMR in response to petitions for rulemaking submitted by shippers, carriers, manufacturers, and industry representatives. These proposed revisions are intended to reduce regulatory burdens while maintaining or enhancing the existing level of safety. We discuss the petitions and proposals in detail in Section II of this NPRM. The following is a brief summary of the proposed regulatory changes:

- Revise approved testing methods for aerosols.
- Revise a table related to cargo tank specifications.
- Update the IBR citation for chlorine tank cars.
- Address inconsistencies between international and domestic labels.
- Revise the vessel requirement to notify the Captain of the Port (COTP) to the presence of limited quantities of hazardous materials.
- Revise testing requirements for packages to allow liquids to be used in place of solid materials.
- Add a shipping description for roadway striping vehicles.
- Extend the service life of tank cars authorized under HM–246 to the full service life of other tanks cars authorized under § 215.203 of the Federal Railroad Administration (FRA) regulations.
- Permit the use of pallets made of non-wood materials for limited quantities.
- Revise requirements for when emergency response numbers are required for excepted quantities.
- Change units for limited quantities of ethyl alcohol to the International System of Units.

- Propose changes concerning valve requirements for cylinders as outlined in "CGA V–9–2012, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, Seventh Edition."
- Incorporate CGA standard "CGA C–7–2014, Guide to Classification and Labeling of Compressed Gases, Tenth Edition."
- Remove requirement for the marking of the service pressure on DOT 8 and DOT 8L cylinders.
- Revise recordkeeping requirements for certain cargo tanks certified in accordance with the ASME Code.
- Revise the printing tolerances for label and placard sizes.
- Incorporate Department of Defense (DoD) explosives manual into § 171.7.
- Allow use of electronic manifest.
- Amend the HMR to acknowledge that the marked date of manufacture on a composite Intermediate Bulk Container (IBC) may differ from the marked date of manufacture on the inner receptacle of that IBC.
- Revise the basis weight tolerance provided in § 178.516(b)(7) from ± 5 percent to ± 10 percent from the nominal basis weight reported in the initial design qualification test report for 4G boxes.

II. Summary Review of Proposed Amendments

A. Testing for Aerosols

In its petition (P–1606), the Council on Safe Transportation of Hazardous Articles (COSTHA) requested that PHMSA allow alternative testing methods, such as those identified in Sections 6.2.4.2.2 and 6.2.4.3 of the United Nations (UN) Model Regulations, to the hot water bath test for aerosols currently found in § 173.306(a)(3)(v) of the HMR. Specifically, COSTHA requested that § 173.306(a)(3) be revised to allow the hot water bath test to be used for aerosols as is allowed in the UN Model Regulations.

On February 22, 2016, PHMSA published a final rule under Docket HM–233F entitled "Adoption of Special Permits" [81 FR 3635] incorporating special permits that allow for alternatives to the hot water bath test similar to those found in the UN Model Regulations. PHMSA believes these alternatives to the hot water bath test satisfy the intent of this petition and it is no longer necessary to propose any new regulatory text at this time.

B. Cargo Tank Specification

In its petition (P–1615), The Walker Group requested revisions to the table in § 180.407(g)(1)(iv) to make this section consistent with the applicable packaging specification (*e.g.,* § 178.347). A cargo tank manufactured to the requirements of the applicable DOT specifications has to be tested in accordance with the HMR. Currently, the design specifications for cargo tanks in § 178.320 contain general requirements applicable to all cargo tanks. The design specifications, including the test pressures for older cargo tanks that are no longer authorized for manufacture but still authorized for use, were last found in the 1985 edition of the HMR (*e.g.,* MC 306—§ 178.341–7; MC 307—§ 178.342–7; MC 312—§ 178.343–7).

This petition seeks to eliminate confusion by changing the regulations to allow the use of the marked test pressure on the cargo tank nameplate as the requalification test pressure and to amend every test pressure entry in the § 180.407(g)(1)(iv) test pressure table by beginning the entries with the phrase, "The test pressure on the nameplate (specification plate)." PHMSA conducted both a technical and policy review of the petition, and instead of modifying every test pressure entry as suggested by the petitioner, PHMSA is proposing that revisions should only apply to certain cargo tank specifications (DOT 407, MC 304, and MC 307) to harmonize the periodic hydrostatic testing required by part 180 with the initial testing for the applicable packaging specification prescribed in part 178. The revisions should further clarify that test pressures (in case of periodic pneumatic testing required by part 180) are already consistent with the initial testing for the applicable packaging specification prescribed in part 178.

C. Chlorine Institute Publications

In its petition (P–1619), the Chlorine Institute requested that updates to publications currently listed in § 171.7(l)—specifically § 171.7(l)(1), (2), (5), and (12)—and referenced in various sections of the HMR be incorporated by reference. PHMSA has conducted a review of these publications and found them suitable to propose incorporation into the HMR. Therefore, PHMSA is proposing to include the following updated documents in the referenced material:

- Chlorine Institute Emergency Kit "A" for 100-lb. & 150-lb. Chlorine Cylinders, Edition 12, Revision 2, July 2014.
- Chlorine Institute Emergency Kit "B" for Chlorine Ton Containers, Edition 11, Revision 1, July 2014.
- Pamphlet 57, Emergency Shut-Off Systems for Bulk Transfer of Chlorine, Edition 6, June 2015.
- Pamphlet 168, Guidelines for Dual Valve Systems for Bulk Chlorine Transport, Edition 2, July 2015.

D. International Label and Placard Consistency

In its petition (P–1620), Labelmaster Services requested revisions to the HMR to address inconsistencies between international and domestic labels and placards. Specifically, the petition requested revisions to §§ 172.519(f) and 172.407(f) of the HMR to allow for the use of labels and placards conforming to the specifications in the UN Recommendations on the Transport of Dangerous Goods, the International Civil Aviation Organization (ICAO) Technical Instructions on the Safe Transport of Dangerous Goods by Air, the International Maritime Dangerous Goods (IMDG) Code, or the Transport Canada Transportation of Dangerous Goods (TDG) Regulations.

After reviewing the petition, PHMSA found that the requested changes are likely to clarify some regulatory requirements and provisions that exist for the transportation of hazardous materials internationally, yet are not likely to be onerous or costly for the regulated community. Therefore, PHMSA is proposing revisions to §§ 172.519(f) and 172.407(f) of the HMR to allow for the use of labels and placards conforming to the specifications in the UN Recommendations, ICAO Technical Instructions, the IMDG Code, or the Transport Canada TDG Regulations.

E. Limited Quantities of Ammonium Nitrate by Vessel

In its petition (P–1624), Horizon Lines, LLC requested that § 176.415(b) be revised to except limited quantities of "UN1942, Ammonium nitrate" from requiring permission from the Captain of the Port (COTP) before being loaded or unloaded from a vessel at a waterfront facility. This petition for rulemaking is in response to previous changes to the HMR that eliminated the Other Regulated Materials Domestic (ORM–D) classification.

Specifically, Horizon Lines expressed concern that while the change from ORM–D to limited quantities is good for harmonization and the industry overall, the change has had some unintended negative consequences for shippers and vessel operators, including "UN1942, Ammonium nitrate" products shipped as ORM–D having to be reclassified under the limited quantities exception. Currently, the HMR require that "UN1942, Ammonium nitrate, 5.1" be moved under a United States Coast

Guard (USCG) permit regardless of the quantity shipped.

In its review of the petition, PHMSA found that shipping "UN1942, Ammonium nitrate, 5.1" as a limited quantity instead of ORM–D will put a higher burden of cost on both the shipper and the vessel operator, without increasing safety, because they must continue to abide by the requirements in § 176.415(c)(4) to obtain a permit. Section 176.415(b) already provides exceptions for "UN1942, Ammonium nitrate" when shipped in a rigid packaging with a noncombustible inside packaging and "UN2067, Ammonium nitrate fertilizer" when the nearest COTP is notified at least 24 hours in advance of any loading or unloading in excess of 454 kg (1,000 pounds). Therefore, PHMSA is proposing an exception for "UN1942, Ammonium nitrate" when shipped as a limited quantity to require written notification to the USCG 24 hours prior to loading this type of cargo.

F. Use of Combination Packages Tested With a Liquid

In its petition (P–1625), HAZMATPAC requested the allowance of the shipment of solid materials in a package when that package has been tested with a liquid material. Currently, § 173.24a(b)(3) allows a single or composite non-bulk packaging that is tested and marked for a liquid hazardous material to be filled with a solid hazardous material up to a gross mass in kilograms not exceeding the rated capacity of the packaging in liters, multiplied by the specific gravity of the packaging, or 1.2 if not marked. In addition, paragraphs (i), (ii), and (iii) allow a packaging rated for a liquid Packing Group I to be filled with a solid Packing Group II hazardous material, a packaging rated for a liquid Packing Group I to be filled with a solid Packing Group III hazardous material, and a packaging rated for a liquid Packing Group II to be filled with a solid Packing Group III hazardous material, all with slightly higher allowable gross masses of such solids.

PHMSA conducted both a technical and economic policy review of the HAZMATPAC petition and found it to merit a rulemaking. Therefore, PHMSA is proposing to revise § 173.24a(b)(3) to allow combination packages tested with liquids to transport solid materials.

G. Shipping Names for Roadway Striping Vehicles

In its petition (P–1634), 3M Company requested an amendment to the table in § 173.5a(c)(l) to include an additional hazardous material description for transport in roadway striping vehicles. Specifically, 3M requested the addition of UN2735 "Amines, Liquid, Corrosive, n.o.s., 8, III" or "Polyamines, Liquid, Corrosive, n.o.s., 8, III" when used as a catalyst.

The table in § 173.5a(c)(1) currently lists "UN3267, Corrosive liquid basic, organic, n.o.s." as a catchall for corrosive liquids while at the same time § 172.101(c)(10)(iii) reads, "A mixture or solution not identified in the Table specifically by name, comprised of two or more hazardous materials in the same hazard class, shall be described using an appropriate shipping description (*e.g.,* 'Flammable liquid, n.o.s.')." The excerpt further states that commodities that can be described explicitly (not comprised of two or more hazardous materials) should be listed by "the name that most appropriately describes the material," with the example being an alcohol not listed by its technical name in the table being described as "Alcohol, n.o.s" rather than "Flammable liquid, n.o.s." Because an amine compound is the single hazardous corrosive component in 3M's pavement marking liquid, PHMSA believes this change will not result in measurable economic or safety impacts. Therefore, PHMSA is proposing to add proper shipping names to § 173.5a(c)(1) to the list of authorized materials that can be used under this section.

H. Toxic by Inhalation Tank Car Lifespan

In its petition (P–1636), the Chlorine Institute requested that PHMSA extend the service life of interim compliant toxic inhalation hazard (TIH) tank cars to the full service life of all other tank cars as allowed in § 215.203 of the FRA regulations. Specifically, the Chlorine Institute requested a revision to paragraph § 173.31(e)(2)(iii), which specifies a 20-year allowable service life for tank cars transporting TIH materials that were built to specifications contemplated in the HM–246 rulemaking because of an expected delay of at least 8 to 10 years before a permanent TIH design standard and specification would be available from the Advanced Tank Car Collaborative Research Program (ATCCRP).

Although the plain language of § 173.31(e)(2)(iii) limits the authorized service life of tank cars meeting the relevant specifications to 20 years from the date of the cars' construction, the final rule in which PHMSA adopted this 20-year service life made clear that tank cars built to these specifications were intended as an interim solution to then-existing market conditions. See [74 FR 1770 (Jan. 13, 2009)]. These interim tank car specifications were intended to make immediate safety improvements in tank car construction and to ensure the ongoing availability of tank cars for the transportation of TIH materials while the Department moved forward with the development and validation of an enhanced performance standard for TIH tank cars and the incorporation of such an enhanced standard into the HMR. With the understanding of the interim nature of these cars, PHMSA intended the 20-year authorized service life to guarantee tank car owners a reasonable service life for the cars, even if the Department were to issue a new tank car standard in the years immediately following the 2009 final rule [74 FR 1770]. The Department is still working towards developing and implementing an enhanced performance standard for TIH materials tank cars. PHMSA's review of the petition found that there is likely economic merit in undertaking a rulemaking as requested. Therefore, PHMSA is proposing to revise § 173.31(e)(2)(iii) to remove the 20-year service life, which will allow continued use of the interim compliant TIH tank cars to the full service life of all other tank cars, as allowed in § 215.203.

I. Limited Quantity Pallets

In its petition (P–1638), Labelmaster Services requested a revision to the HMR that would allow the use of plastic or metal pallets to transport materials classed and marked as limited quantities. The petition specifically requested that PHMSA revise § 173.156(b)(2)(iii), which specifies these materials be secured to a wooden pallet, to also specify that they could be secured to a plastic or metal pallet.

PHMSA's review of the petition found that there is likely economic merit in undertaking a rulemaking as requested. In addition, a technical review of the petition found there should be no decrease in safety due to the proposed change. The changes suggested by this petition would allow transporters greater flexibility in their choice of pallets, with possible accompanying cost savings. Therefore, PHMSA is proposing to revise § 173.156(b)(2)(iii) to allow for the use of metal, plastic, or composite pallets used to ship limited quantities of hazardous materials.

J. Emergency Response Numbers

In its petition (P–1639), Horizon Lines, LLC requested an exception to the requirement in § 172.604(d)(1) to provide an emergency response telephone number in order to no longer require an emergency response telephone number be provided on a shipping paper for excepted quantities of hazardous materials. This change would be consistent with how PHMSA treats limited quantities of hazardous materials. Specifically, the petition asked PHMSA to revise § 172.604(d)(1) in order for it to be applicable to limited quantities and excepted quantities.

This modification is justified in that excepted quantity weights are less than the already exempted limited quantity weights. In addition, this revision will harmonize the emergency response number requirements with the IMDG Code, which does not require an emergency response telephone number on the dangerous goods documentation (or anywhere else) for any excepted material; however, all hazardous materials, including those in excepted quantities, must comply with Section 5.4.3.2 of the IMDG Code, which requires emergency response information to be communicated in ways other than a phone number, such as a Safety Data Sheet (SDS). PHMSA's review of the petition found that there is likely economic merit in undertaking a rulemaking as requested without any decrease to safety. Therefore, PHMSA is proposing to revise § 172.604(d)(1) to no longer require an emergency response telephone number on a shipping paper be provided for excepted quantities of hazardous materials.

K. Units of Measurement for Limited Quantities of Ethyl Alcohol

In its petition (P–1640), the Association of HAZMAT Shippers requested that the units of measure included in § 173.150(g) be converted to the International System of Units, as they are expressed elsewhere in the HMR. The International System of Units is typically used in the manufacturing of inner receptacles. PHMSA's review of the petition found that there is likely economic merit in undertaking a rulemaking as requested without any decrease to safety. Therefore, PHMSA is proposing to revise § 173.150(g) to convert measurements to the International System of Units.

L. Cylinder Valves and Protection Caps

In its petition (P–1641), CGA proposed to add new paragraphs § 173.301(a)(11) and (12). The proposed changes concern valve requirements for cylinders as outlined in "CGA V–9–2012, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, Seventh Edition."

Specifically, CGA requests that cylinder valves and cylinder valve protection caps manufactured on or after May 4, 2015, be required to conform to the requirements in "CGA V–9–2012, Compressed Gas Association Standard for Compressed Cylinder Valves, Seventh Edition." Justifications for this request include ensuring standardization of cylinder valve designs and providing guidance to users on proper selection of valves. PHMSA's review of the petition found that there is likely economic merit in undertaking a rulemaking as requested without any decrease to safety. Therefore, PHMSA is proposing to add new paragraphs § 173.301(a)(11) and (12) to the HMR to conform to the new standards for cylinder valves and caps as outlined in "CGA V–9–2012, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, Seventh Edition."

M. Recordkeeping Requirements for Portable Tanks

In its petition (P–1644), HAZMAT Resources proposed to add text to § 180.605(l) to address recordkeeping requirements for portable tanks. This revision would harmonize this recordkeeping requirement with § 180.417(a)(3)(ii), which addresses recordkeeping requirements for certain cargo tank motor vehicles constructed and certified in accordance with the ASME Code. The petitioner recommends renaming § 180.605(l) to § 180.605(l)(1) and adding an additional § 180.605(l)(2). This new section would include recordkeeping requirements in line with § 180.417(a)(3)(ii). PHMSA agrees that not harmonizing recordkeeping requirements for portable tanks and cargo tank motor vehicles was an oversight and that this revision as proposed would provide an alternative means of compliance for portable tanks that has already been provided for cargo tanks. PHMSA believes there is likely economic merit in revising this section without a reduction in safety. The inclusion of a similar section in an already published § 180.407(a)(3)(ii) increases the validity of this proposed change. Therefore, PHMSA is proposing to revise § 180.605(l) to allow the owner of a portable tank to contact the National Board for a copy of the manufacture's data report, if the portable tank was registered with the National Board, or copy the information contained on the portable tanks specification plate and ASME Code data plates.

N. Printing Tolerances for Labels and Placards

In its petition (P–1650), Labelmaster Services proposed to revise §§ 172.407(c) and 172.519(c) of the HMR to allow for printing tolerances for labels and placards. Labelmaster noted that the printing tolerances specified for the solid-line inner border that is parallel to the edge is extremely difficult to maintain with standard printing processes.

After a policy review of the petition, PHMSA agrees with Labelmaster that the absence of a tolerance will increase printing costs, as well as lead to inconsistent enforcement practices and confusion on the part of businesses attempting to remain compliant, without providing any increase in safety or hazard communication. Therefore, PHMSA is proposing to revise §§ 172.407(c) and 172.519(c) to add the word "approximately" to these sections to allow for printing tolerances with respect to the solid inner border for labels and placards. PHMSA believes that this simple fix and small change in the HMR could reduce costs with no degradation in safety.

O. Incorporation of Department of Defense Standards

In its petition (P–1651), the Department of Defense (DoD) Explosives Safety Board requested that PHMSA amend the citations in § 171.7(o)(1) and (2) to include the latest detailed publications used by the DoD in its examination and classification of explosives. PHMSA reviewed and provided feedback to DoD on the proposed changes to the manuals. Updating this manual is essential to allowing the DoD to safely move explosives in the interest of national security. Therefore, PHMSA is proposing to incorporate these documents into the HMR as requested.

P. Definitions for "Basic Description" and "Shipping Description"

In its petition (P–1655), the Dangerous Goods Trainers Association (DGTA) proposed that PHMSA revise § 171.8 to add definitions for "Basic Description" and "Shipping Description." The DGTA specifically suggested that adding these definitions to the HMR will provide vital clarification to the meaning of these terms. The DGTA informed PHMSA that its members often receive questions from trainees about the terms "basic description" and "shipping description," which are used to describe the information required on shipping papers in accordance with part 172, subpart C of the HMR—Shipping Papers. The petition proposes definitions be provided for "basic description" and "shipping description" in § 171.8, along with amendments to the HMR to ensure that these terms are used consistently and appropriately. PHMSA believes there is likely merit in adding these definitions without a reduction in safety. Therefore, PHMSA is proposing definitions for "basic description" and "shipping description" in § 171.8 of the HMR.

Q. Service Pressure Marking for DOT 8 and DOT 8L Cylinders

In its petition (P–1656), Norris Cylinder proposed that PHMSA revise § 178.35(f)(7) to no longer require the marking of the service pressure on DOT 8 and DOT 8L cylinders. After both a technical and policy review of the petition, PHMSA agrees with Norris Cylinder that it was never the intention to require the marking of the service pressure on DOT 8 and DOT 8L cylinders. Therefore, PHMSA is proposing to revise this section as requested by the petitioner.

R. Incorporation of CGA Publication

In its petition (P–1657), CGA proposed to IBR updates to the CGA publication "CGA C–7–2014, Guide to Classification and Labeling of Compressed Gases, Tenth Edition" currently listed in § 171.7(n)(7). This IBR has been updated to meet requirements for the U.S. Occupational Health and Safety Administration (OSHA) and was previously incorporated into OSHA's regulations in 2012. The CGA is requesting that PHMSA permit the use of the 2014 edition of CGA C–7 to keep the DOT current with industry practices that are incorporated into Appendix A of C–7.

PHMSA's review of the petition found that there are some editorial changes to the text of Appendix A in the 2014 edition that were added for clarity but do not impact the use of the required labels. Therefore, PHMSA is proposing the incorporation by reference of "CGA C–7–2014, Guide to Classification and Labeling of Compressed Gases, Tenth Edition" into the HMR.

S. Use of Electronic Manifest

In its petition (P–1659), COSTHA proposed to revise § 172.205 to permit the use of electronic signatures when completing an EPA form 8700–22 and 8700–22A. PHMSA reviewed and concurred with this proposed change, believing there is likely merit without a reduction in safety. Therefore, PHMSA is proposing to add paragraph (j) to permit the use of electronic signatures when completing an EPA form 8700–22 and 8700–22A.

T. Marked Date of Manufacture on Composite IBCs

In its petition (P–1662), Rigid Intermediate Bulk Container Association of North America (RIBCNA) proposed to amend § 178.703(b) to acknowledge that the marked date of manufacture on a composite IBC may differ from the marked date of manufacture on the inner receptacle of that IBC. The RIBCNA petitioned PHMSA to propose the substance of the UN adopted note, "The date of manufacture of the inner receptacle may be different from the marked date of manufacture (see 6.5.2.1), repair (see 6.5.4.5.3) or remanufacture (see 6.5.2.4) of the composite IBC," as a final sentence in § 178.703(b)(6)(i) to read as follows: "The date of manufacture of the inner receptacle may be different from the marked date of manufacture required by § 178.703(a)(1)(iv) or by § 180.352(d)(1)(iv)."

After a review of the petition, PHMSA found that allowing the inner receptacle and the composite IBC to have different date markings will have no effect on the safety of the use and manufacture of IBCs. Integrating the proposed language into the current HMR will also bring rules governing markings of IBCs more in line with current international standards. Therefore, PHMSA is proposing a change to the HMR to allow the date of manufacture on the inner receptacle to be different than on the composite IBC.

U. Basis Weight Tolerances for Liners and Mediums Used in the Manufacture of Specification UN 4G Fiberboard Boxes

In its petition (P–1663), COSTHA requested PHMSA revise the basis weight tolerance provided in § 178.516(b)(7) from +/−5 percent to +/−10 percent from the nominal basis weight reported in the initial design qualification test report.

PHMSA conducted a review of the petition and found that the requested change is unlikely to affect safety in any way and is largely following industry practices. The realities of paper manufacturing are such that a wide range of basis weights can be found on any large enough sample of fiberboard run on the same line to the same specification. This revision would only modify the percentage threshold for the allowable nominal basis weight for fiberboard boxes and would not result in any fundamental changes to testing, recordkeeping, or approval processes by either PHMSA or the regulated community. Therefore, PHMSA is proposing to revise the basis weight tolerance provided in § 178.516(b)(7) from +/−5 percent to +/−10 percent from the nominal basis weight reported in the initial design qualification test report.

III. Section-by-Section Review

Below is a section-by-section description of the changes being proposed in this NPRM.

A. Section 171.7

Section 171.7 lists all standards incorporated by reference into the HMR that are not specifically set forth in the regulations. This NPRM proposes to incorporate by reference publications by the Chlorine Institute, the DoD, and the CGA.

The Chlorine Institute publications include the following:

1. Chlorine Institute Emergency Kit "A" for 100-lb. & 150-lb. Chlorine Cylinders, Edition 12, Revision 2, July 2014. This publication is freely available on the Chlorine Institute Web site at: *https://bookstore.chlorineinstitute.org/iba-instruction-booklet-chlorine-institute-emergency-kit-a-for-100-lb-and-150-lb-chlorine-cylinders-166.html*. This publication provides instructions and illustrates the use of Chlorine Institute Emergency Kit 'A'. This booklet provides instructions for both generations of Emergency Kit 'A', those manufactured before 12/31/12 and after 1/1/13. It also includes complete parts list for both generations.;

2. Chlorine Institute Emergency Kit "B" for Chlorine Ton Containers, Edition 11, Revision 1, July 2014. This publication is available on the Chlorine Institute Web site at: *https://bookstore.chlorineinstitute.org/mm5/merchant.mvc?Session_ID=832f559635b70c753d7a6780f48760946&Store_Code=ci2store&Screen=PROD&Product_Code=EPR_IB_B-HC&*. This publication provides instructions and illustrates the use of Chlorine Institute Emergency Kit "B." Includes complete parts list. Depictions of commonly used optional devices were added to this edition and numerous editorial revisions were made. In addition, instructions on how to apply both the current and previous kit devices of Emergency Kit "B" are included.

3. Pamphlet 57, Emergency Shut-Off Systems for Bulk Transfer of Chlorine, Edition 6, June 2015. This publication is available on the Chlorine Institute Web site at: *https://bookstore.chlorineinstitute.org/mm5/merchant.mvc?Session_ID=832f559635b70c753d7a6780f48760946&Store_Code=ci2store&Screen=PROD&Product_Code=SPHP0057-HC&*. This publication describes recommended practices for emergency shut-off protection during chlorine transfers involving bulk containers.

4. Pamphlet 168, Guidelines for Dual Valve Systems for Bulk Chlorine

Transport, Edition 2, July 2015. Pamphlet 168 is to be added to the HMR at § 178.337–9. This publication is available on the Chlorine Institute Web site at: *https://bookstore.chlorineinstitute.org/mm5/merchant.mvc?Session_ID=832f559635b70c753d7a6780f4876094&Store_Code=ci2store&Screen=PROD&Product_Code=SPHP0168-HC&*. This publication sets forth performance/selection criteria that should be utilized in identifying dual valve systems for bulk chlorine transportation applications (*i.e.*, tank cars, cargo tanks and barges). These configurations are intended to meet DOT and Transport Canada (TC) performance requirements. This pamphlet contains information pertaining to standardizations, performance/design criteria, operational considerations and installation considerations, as well as an appendix that includes valve manufacturer information.

DoD publications include the following:

1. TB 700–2; NAVSEAINST 8020.8C; TO 11A–1–47: DoD Ammunition and Explosives Hazard Classification Procedures, 30 July 2012, into § 173.56. This publication is freely available on the DoD Web site at: *https://www.ddesb.pentagon.mil/docs/TB700-2.pdf*. This publication sets forth detailed procedures for hazard classifying ammunition and explosives in accordance with DOT regulations, North Atlantic Treaty Organization guidelines, and United Nations recommendations.

2. DLAR 4145.41/AR 700–143/NAVSUPINST 4030.55D/AFMAN 24–210_IP/MCO 4030.40C: Packaging of Hazardous Materials, 21 April 2015 into § 173.7. This publication is freely available on the DoD Web site at: *http://www.dla.mil/Portals/104/Documents/J5StrategicPlansPolicy/PublicIssuances/r4145.41.pdf*. This publication reissues establishes uniform policy for packaging hazardous materials for safe, efficient, and legal storage, handling, and transportation, to include Department of Transportation Special Permit (DOT–SP), Competent Authority Approval (CAA), Certificate of Equivalency (COE) and Packaging Waivers for Military Air in accordance with AR 700–15/NAVSUPINST 4030.28E/AFJMAN 24–206/MCO 4030.33E/DLAR 4145.7 (Reference (c)) and Defense Transportation Regulation (DTR) 4500.9- R-Part II, Cargo Movement (Reference (d)).

CGA publications include the following:

1. "CGA C–7–2014, Guide to Classification and Labeling of Compressed Gases, Tenth Edition. During the open comment period of this NPRM, this publication is freely available on the CGA Web site at: *https://www.cganet.com/customer/dot.aspx*. This publication states the general principles for labels and markings and give recommended minimum requirements for many hazardous gases and selected liquids.

2. CGA V–9, 2012, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, Seventh Edition. During the open comment period of this NPRM, this publication is freely available on the CGA Web site at: *https://www.cganet.com/customer/dot.aspx*. This publication specifies general cylinder valve design, design qualification, required markings, and performance requirements such as operating temperature limits, pressure ranges, operating torque limits, and flow capabilities. Also provided are testing and maintenance requirements.

B. Section 172.205

Section 172.205 describes the requirements for the use of hazardous waste manifest. This NPRM proposes to add paragraph (j) to permit the use of electronic signatures when completing an EPA form 8700–22 and 8700–22A.

C. Section 172.407

Section 172.407 describes the label specifications for packages shipping hazardous materials under the HMR. This NPRM proposes to revise paragraph (c) to allow for size tolerances for the labels by inserting the term "approximately" for the inner border to be 5 mm. This NPRM also proposes to revise paragraph (f) to address inconsistencies between international and domestic labels.

D. Section 172.519

Section 172.519 describes placard specification for shipments of hazardous materials that require placards. This NPRM proposes to revise paragraph (c) to allow for size tolerances for the placards by inserting the term "approximately" for the inner border to be 5 mm.

E. Section 172.604

Section 172.604 describes the requirements to have an emergency response number on shipping papers for shipments of hazardous materials. This NPRM proposes to no longer require an emergency response number for excepted quantities of hazardous materials by revising § 172.604(d).

F. Section 173.5a

Section 173.5a outlines the requirements for cargo tank motor vehicles used for roadway striping. This NPRM proposes to add proper shipping names to § 173.5a(c)(1) to the list of authorized materials that can be used under this section.

G. Section 173.24a

Section 173.24a outlines the general requirements for non-bulk packages. This NPRM proposes to revise each paragraph in this section to allow for packages tested with a liquid material to be filled with a solid material of the equivalent packing group.

H. Section 173.31

Section 173.31 outlines the specifications for the use of tank cars. Specifically, § 173.31(e) outlines the specifications for tank cars used to transport materials that are poisonous by inhalation. This NPRM proposes to remove the reference to the 20-year service life for these tank cars in § 173.31(e)(2)(iii), thus extending the service life to the standard for all tank cars set forth at § 215.203 of the Federal Railroad Administration (FRA) regulations.

I. Section 173.150

Section 173.150 outlines exceptions for Class 3 flammable and combustible liquids. This NPRM proposes to change the units in § 173.150(g) from imperial units to the International System of Units and to revise all the units in this section to the International System of Units.

J. Section 173.156

Section 173.156 outlines exceptions for limited quantities and ORM–D materials. This NPRM proposes to revise § 173.156(b)(2)(iii) to allow for pallets to be made of metal, plastic, or composite materials in addition to wood.

K. Section 173.301

Section 173.301 outlines the general requirements for the shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles, and spherical pressure vessels. This NPRM proposes to revise § 173.301(a) by adding subparagraphs (11) and (12). Paragraph (11) will require all cylinder valves manufactured on or after May 4, 2015, to conform to the requirements in CGA V–9–2012, as well as requiring UN pressure receptacles to conform to the requirements of § 173.301b(c)(1). Paragraph (12) will require that cylinder valve protection caps manufactured on or after May 4, 2015, conform to the requirements of CGA V–9–2012. Cylinder valve protection caps used on UN cylinders must conform to the requirements in § 173.301b(c)(2)(ii).

L. Section 173.306

Section 173.306 outlines the requirements for limited quantities of compressed gases. This NPRM proposes to allow alternate test methods to the current hot water bath test in the UN Model Regulations.

M. Section 176.415

Section 176.415 outlines permit requirements for Division 1.5, ammonium nitrates, as well as certain ammonium nitrate fertilizers. This NPRM proposes to no longer require written permission from the COTP to load or unload limited quantities of ammonium nitrates.

N. Section 178.35

Section 178.35 outlines the general requirements for specification cylinders. This NPRM proposes to revise § 178.35 to no longer require the marking of the service pressure for DOT 8 and DOT 8 AL cylinders.

O. Section 178.337

Section 178.337–9 outlines the requirements for pressure relief devices, piping, valves, hoses, and fittings. This NPRM proposes to revise § 178.337–9(b)(8) to add a reference to allow the use of "Sections 4 through 6, Pamphlet 168, Guidelines for Dual Valve Systems for Bulk Chlorine Transport, Edition 1, February 2013" under this section.

P. Section 178.516

Section 178.516 outlines the standards for fiberboard boxes. This NPRM proposes to revise § 178.516(b)(7) to allow for the paper wall basis weights that vary by not more than +/−10 percent from the nominal basis weight reported in the initial design qualification test report.

Q. Section 178.703

Section 178.703 outlines the marking requirements for IBCs. This NPRM proposes to revise § 178.703(b)(6)(i) by clarifying that the date of manufacture of the inner receptacle may be different from the marked date of manufacturer required by § 178.703(a)(1)(iv) or § 180.352(d)(1)(iv) provided that the retest and inspection of the IBCs be based on the EARLIEST marked date.

R. Section 180.407

Section 180.407 outlines the requirements for the testing and inspection of specification cargo tanks. This NPRM proposes to revise the table in § 180.407(g)(1)(iv) to put the words "the test pressure on the name plate" in the test pressure column before each test pressure specification.

S. Section 180.605

Section 180.605 outlines the requirements for periodic testing, inspection, and repair of portable tanks. This NPRM proposes to revise § 180.605(l) by adding § 180.605(l)(2) to allow the owner of a portable tank to contact the National Board for a copy of the manufacture's data report, if the portable tank was registered with the National Board, or copy the information contained on the portable tank's specification plate and ASME Code data plates.

IV. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This NPRM is published under authority of the Federal Hazardous Materials Transportation Law (Federal Hazmat Law; 49 U.S.C. 5101 *et seq.*). Section 5103(b) of Federal Hazmat Law authorizes the Secretary of Transportation to prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce.

B. Executive Order 12866, Executive Order 13563, Executive Order 13610, and DOT Regulatory Policies and Procedures

This NPRM is not considered a significant regulatory action under Section 3(f) of Executive Order 12866 ("Regulatory Planning and Review") and, therefore, was not reviewed by the Office of Management and Budget (OMB). The proposed rule is not considered a significant rule under the Regulatory Policies and Procedures order issued by the U.S. Department of Transportation [44 FR 11034].

Background

Executive Orders 12866 ("Regulatory Planning and Review") and 13563 ("Improving Regulation and Regulatory Review") require agencies to regulate in the "most cost-effective manner," to make a "reasoned determination that the benefits of the intended regulation justify its costs," and to develop regulations that "impose the least burden on society."

Executive Order 13563 ("Improving Regulation and Regulatory Review") supplements and reaffirms the principles, structures, and definitions governing regulatory review that were established in Executive Order 12866 of September 30, 1993. In addition, Executive Order 13563 specifically requires agencies to: (1) Involve the public in the regulatory process; (2) promote simplification and harmonization through interagency coordination; (3) identify and consider regulatory approaches that reduce burden and maintain flexibility; (4) ensure the objectivity of any scientific or technological information used to support regulatory action; and (5) consider how to best promote retrospective analysis to modify, streamline, expand, or repeal existing rules that are outmoded, ineffective, insufficient, or excessively burdensome.

Executive Order 13610 ("Identifying and Reducing Regulatory Burdens"), issued May 10, 2012, urges agencies to conduct retrospective analyses of existing rules to examine whether they remain justified and whether they should be modified or streamlined in light of changed circumstances, including the rise of new technologies.

PHMSA has involved the public in the regulatory process in a variety of ways for this proposed rulemaking. Specifically, in this rulemaking PHMSA is responding to 25 petitions that have been submitted by the public in accordance with the Administrative Procedure Act and PHMSA's rulemaking procedure regulations (49 CFR 106.95). Key issues covered by the petitions include requests from the public to revise packaging requirements and incorporate multiple publications by reference.

Affected Entities

This NPRM proposes regulatory changes responding to 25 petitions that have been submitted by the public. This NPRM would affect some PHMSA stakeholders, including hazardous materials shippers and carriers by highway, rail, vessel, and aircraft, as well as package manufacturers and testers.

Summary of Costs

PHMSA anticipates the proposals contained in this rule will have minimal costs. For the purposes of analysis PHMSA grouped the proposed amendments by the type of change they implement. These groupings include Harmonization, Regulatory Clarity/Editorial, Regulatory Flexibility, and Incorporation of Standards. We discuss qualitatively the cost of these groupings below.

Harmonization. PHMSA believes that this proposed set of amendments aimed at harmonizing the HMR with international standards will increase standardization and consistency of regulations, which will result in minimal costs. However, if the changes in this proposed rule are not adopted in the HMR, U.S. companies, including numerous small entities competing in foreign markets, would be at an economic disadvantage. These companies would be forced to comply with a dual system of regulations. The changes in this proposed rulemaking are intended to avoid this result.

Regulatory Clarity/Editorial. PHMSA believes that this proposed set of amendments aimed at improving regulatory clarity and making editorial changes would have no cost. These amendments simply clarify existing requirements to improve compliance.

Regulatory Flexibility. PHMSA believes that this proposed set of amendments aimed at regulatory flexibility would have no cost. These amendments would provide alternative methods of compliance while retaining current HMR requirements. Those stakeholders impacted by these changes would have the regulatory flexibility to choose the most beneficial (*e.g.* least costly) manner of compliance.

Incorporation of Standards. PHMSA believes that this proposed set of amendments aimed at incorporating consensus industry standards will have a marginal cost. This cost would be the cost of purchasing the appropriate industry standard.

Summary of Benefits

While PHMSA anticipates that the proposals contained in this rule will have minimal costs, there are corresponding benefits that exceed those costs. For the purposes of analysis PHMSA grouped the proposed amendments by the type of change they implement. These groupings include Harmonization, Regulatory Clarity/Editorial, Regulatory Flexibility, and Incorporation of Standards. We discuss qualitatively the benefits of these groupings below.

Harmonization. PHMSA believes that this proposed set of amendments aimed at harmonizing the HMR with international standards will increase standardization and consistency of regulations, which will result in overall marginal benefits. Adopting these amendments would enhance transportation safety by increasing the consistency of domestic and international hazard hazardous materials transportation regulations. American manufacturers of hazardous materials would also benefit with continued access to foreign markets. Shippers engaged in domestic and international commerce, including trans-border shipments within North America would save money and experience fewer regulatory burdens.

Regulatory Clarity/Editorial. PHMSA believes that this proposed set of amendments aimed at improving regulatory clarity and making editorial changes would have no cost but may foster greater compliance and improved safety. This greater compliance could result in the benefit of decreased hazardous materials related injuries.

Regulatory Flexibility. PHMSA believes that this proposed set of amendments aimed at regulatory flexibility would provide alternative methods of compliance while retaining current HMR requirements. These alternative methods of compliance would provide an equivalent level of safety to current requirements. Those stakeholders impacted by these changes would have the regulatory flexibility to choose the most beneficial manner of compliance.

Incorporation of Standards. PHMSA believes that this proposed set of amendments aimed at incorporating consensus industry standards will have benefits associated with increased clarity and consistency. In addition, adoption and updating of these standards to current version will insure the most recent best practices and technology are implemented.

Conclusion

In this NPRM, we propose to amend miscellaneous provisions in the HMR to clarify the provisions and to relax overly burdensome requirements. PHMSA anticipates the proposals contained in this rule will have marginal economic benefits to the regulated community with minimal costs. This NPRM is designed to increase the clarity of the HMR, thereby increasing voluntary compliance while reducing compliance costs.

C. Executive Order 13132

This proposed rule was analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). This proposed rule would preempt State, local, and Indian tribe requirements but does not propose any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal Hazardous Materials Transportation Law, 49 U.S.C. 5125(b)(1), contains an express preemption provision (49 U.S.C. 5125(b)) preempting State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(i) The designation, description, and classification of hazardous materials;

(ii) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(iii) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, content, and placement of those documents;

(iv) The written notification, recording, and reporting of the unintentional release in transportation of hazardous materials; or

(v) The design, manufacture, fabrication, marking, maintenance, reconditioning, repair, or testing of a packaging or container which is represented, marked, certified, or sold as qualified for use in the transport of hazardous materials.

This proposed rule concerns the classification, packaging, marking, labeling, and handling of hazardous materials, among other covered subjects. If adopted, this rule would preempt any State, local, or Indian tribe requirements concerning these subjects unless the non-Federal requirements are "substantively the same" as the Federal requirements. (See 49 CFR 107.202(d).)

The Federal Hazardous Materials Transportation Law provides at 49 U.S.C. 5125(b)(2) that if PHMSA issues a regulation concerning any of the covered subjects, PHMSA must determine and publish in the **Federal Register** the effective date of Federal preemption. That effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. PHMSA proposes the effective date of Federal preemption be 90 days from publication of a final rule in this matter in the **Federal Register**.

D. Executive Order 13175

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 ("Consultation and Coordination with Indian Tribal Governments"). Because this proposed rule does not have tribal implications and does not impose substantial direct compliance costs on Indian tribal governments, the funding and consultation requirements of Executive Order 13175 do not apply, and a tribal summary impact statement is not required.

E. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines the rule is not expected to have a significant impact on a substantial number of small entities. This proposed rule would amend miscellaneous provisions in the HMR to clarify provisions based on petitions for rulemaking. While maintaining safety, it would relax certain requirements that are overly burdensome and provide clarity where requested by the regulated community. The proposed changes are generally intended to provide relief to shippers, carriers, and packaging manufacturers, including small entities.

The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where it is possible to do so and still meet the objectives of applicable regulatory statutes. In the case of hazardous materials transportation, it is not possible to establish exceptions or differing standards and still accomplish our safety objectives.

The proposed changes are generally intended to provide relief to shippers, carriers, and packaging manufactures and testers, including small entities. Therefore, this proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule has been developed in accordance with Executive Order 13272 (“Proper Consideration of Small Entities in Agency Rulemaking”) and the DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered.

F. Paperwork Reduction Act

This proposed rule does not impose any new information collection requirements, and in one instance, marginally decreases the information collection burden on the reregulated community. Specifically, the following information collection requirement is affected by this rulemaking:

OMB Control No. 2137–0034: Hazardous Materials Shipping Papers and Emergency Response Information.

Decrease in Annual Number of Respondents: 1,000.

Decrease in Annual Responses: 1,666,667.

Decrease in Annual Burden Hours: 4,629.

Decrease in Annual Burden Cost: $95,403.69.

PHMSA estimates that no longer requiring the emergency response number for limited quantity shipments by vessel will reduce the number of burden hours by 4,629. PHMSA estimates that no longer requiring the emergency response number on shipping paper will save 10 seconds per shipping paper and affect 1,666,667 shipments per year. PHMSA estimates a savings of $.06 per shipment resulting in cost savings of $95,403.69.

Please direct your requests for a copy of this final information collection to Steven Andrews or T. Glenn Foster, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., 2nd Floor, Washington, DC 20590–0001.

G. Regulatory Identifier Number (RIN)

A regulatory identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

H. Unfunded Mandates Reform Act

This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $141.3 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the rule.

I. Environmental Assessment

The National Environmental Policy Act, 42 U.S.C. 4321–4375, requires Federal agencies to analyze proposed actions to determine whether the action will have a significant impact on the human environment. The Council on Environmental Quality (CEQ) regulations require Federal agencies to conduct an environmental review considering: (1) The need for the proposed action; (2) alternatives to the proposed action; (3) probable environmental impacts of the proposed action and alternatives; and (4) the agencies and persons consulted during the consideration process.

Need for the Proposed Action

In response to petitions for rulemaking submitted by the regulated community, PHMSA proposes to amend the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) to update, clarify, or provide relief from miscellaneous regulatory requirements. Specifically, PHMSA is proposing amendments that include, but are not limited to, the following: Incorporating by Reference (IBR) multiple publications from both the Compressed Gas Association (CGA) and the Chlorine Institute; addressing inconsistencies with domestic and international labels and placards; permitting alternative testing for aerosols; excepting excepted quantities from the emergency response telephone requirement; allowing electronic signatures for Environmental Protection Agency (EPA) manifest forms; and no longer requiring the service pressure to be marked on Department of Transportation (DOT) 8 and 8L cylinders.

These amendments are intended to promote safety, regulatory relief, and clarity. The proposed changes were identified in response to petitions from stakeholders affected by the HMR. These proposed minor changes will clarify the HMR and enhance safety, while offering some net economic benefits.

This action is necessary to: (1) Fulfill our statutory directive to promote transportation safety; (2) fulfill our statutory directive under the Administrative Procedure Act (APA) that requires Federal agencies to give interested persons the right to petition an agency to issue, amend, or repeal a rule (5 U.S.C. 553(e)); (3) support governmental efforts to provide regulatory relief to the regulated community; (4) address safety concerns raised by petitioners and remove identified regulatory ambiguity; and (5) simplify and clarify the regulations in order to promote understanding and compliance.

The intended effect of this action is to enhance the safe transportation of hazardous materials and, in conjunction, clarify, simplify, and relax certain regulatory requirements for carriers, shippers, and other stakeholders. These regulatory revisions will offer more efficient and effective ways of achieving the PHMSA goal of safe and secure transportation, protecting both people and the environment, of hazardous materials in commerce.

Alternatives

In proposing this rulemaking, PHMSA is considering the following alternatives:

Alternative 1: No Action

If PHMSA chose this alternative, it would not proceed with any rulemaking on this subject and the current regulatory standards would remain in effect. This option would not address outstanding petitions for rulemaking. We rejected the no action alternative.

Alternative 2: Go Forward With the Proposed Amendments to the HMR in This NPRM

This alternative is the current proposal as it appears in this NPRM, applying to transport of hazardous materials by highway, rail, vessel, and aircraft. The proposed amendments encompassed in this alternative are more fully addressed in the preamble and regulatory text sections of the NPRM.

Probable Environmental Impacts of the Alternatives

When developing potential regulatory requirements, PHMSA evaluates those requirements to consider the environmental impact of each amendment. Specifically, PHMSA evaluates the: Risk of release and resulting environmental impact; risk to human safety, including any risk to first responders; longevity of the packaging; and if the proposed regulation would be carried out in a defined geographic area, the resources, especially any sensitive areas, and how they could be impacted by any proposed regulations. Of the regulatory changes proposed in this rulemaking, most have been determined to be clarification, technology/design updates, harmonization, regulatory flexibility, standard incorporation, or editorial in nature. As such, these amendments have little or no impact on: The risk of release and resulting environmental impact; human safety; or longevity of the packaging. None of these amendments would be carried out in a defined geographic area, *i.e.*, this is a nation-wide rule making.

Alternative 1: No Action

If PHMSA were to select the No Action Alternative, current regulations would remain in place, and no new provisions would be added. However, efficiencies gained through harmonization in updates to transport standards, lists of regulated substances, definitions, packagings, markings requirements, shipper requirements, modal requirements, etc., would not be realized. Foregone efficiencies in the No Action Alternative also include freeing up limited resources to concentrate on hazardous materials transportation issues of potentially much greater environmental impact. Not adopting the proposed environmental and safety requirements in the NPRM under the No Action Alternative would result in a lost opportunity for reducing negative environmental and safety-related impacts. Greenhouse gas emissions would remain the same under the No Action Alternative.

Alternative 2: Go Forward With the Proposed Amendments to the HMR in This NPRM:

The Preferred Alternative encompasses enhanced and clarified regulatory requirements, which would result in increased compliance and less negative environmental and safety impacts. The table below summarizes possible environmental benefits and any potential negative impacts for the amendments proposed in the NPRM. A detailed discussion on the potential environmental impacts of each type of amendment is included in the complete EA placed in the docket for this rulemaking.

SUMMARY OF PROBABLE ENVIRONMENTAL IMPACTS BY AMENDMENTS

Proposed amendment(s) to HMR (lettered as above herein)	Type of amendment(s)	Probable environmental impact(s) anticipated
A. Testing for Aerosols	Harmonization	No impacts—slightly positive benefits.
B. Cargo Tank Specification	Regulatory Clarity	No impacts—slightly positive benefits.
C. Chlorine Institute Publications	Update (Publications)	No impacts—slightly positive benefits.
D. International Label and Placard Consistency	Harmonization	Slightly positive benefits.
E. Limited Quantities of Ammonium Nitrate by Vessel	Exception	No impacts.
F. Use of Combination Packages Tested with a Liquid	Regulatory Flexibility	Very slight, negligible, or no impacts.
G. Shipping Names for Roadway Stripping Vehicles	Editorial	No impacts.
H. Toxic by Inhalation (TIH) Tank Car Lifespan	Regulatory Flexibility	No impacts.
I. Limited Quantity Pallets	Regulatory Flexibility	No impacts—slightly positive benefits.
J. Emergency Response Numbers	Harmonization	No impacts.
K. Units of Measurement for Limited Quantities of Ethyl Alcohol	Harmonization/Editorial	No impacts.
L. Cylinder Valves and Protection Caps	Standard Incorporation	No impacts—slightly positive benefits.
M. Recordkeeping Requirements for Portable Tanks	Regulatory Clarity, Harmonization	No impacts—slightly positive benefits.
N. Printing Tolerances for Labels and Placards	Regulatory Flexibility	Slightly positive benefits.
O. Incorporation of Department of Defense (DoD) Standards	Standard Incorporation	Slightly positive—moderate benefits.
P. Definitions for "Basic Description" and "Shipping Description"	Regulatory Clarity	No impacts—slightly positive impacts.
Q. Service Pressure Marking for DOT 8 and DOT 8L Cylinders	Regulatory Flexibility	No impacts.
R. Incorporation of CGA Publications	Standard Incorporation	No impacts—slightly positive benefits.
S. Use of Electronic Manifest	Update (Technology/Design), Regulatory Flexibility.	No impacts—slightly positive benefits.
T. Marked Date of Manufacture on Composite IBCs	Harmonization	No impacts—slightly positive benefits.
X. Basis Weight Tolerances for Liners and Mediums Used in the Manufacture of Specification UN 4G Boxes.	Regulatory Flexibility	No impacts.

If PHMSA selects the provisions as proposed in this NPRM, we believe that safety and environmental risks would be reduced and that protections to human health and environmental resources would be increased.

Agencies Consulted

This NPRM would affect some PHMSA stakeholders, including hazardous materials shippers and carriers by highway, rail, vessel, and aircraft, as well as package manufacturers and testers. PHMSA sought comment on the environmental assessment contained in the April 26, 2012, NPRM published under Docket PHMSA 2011–0138 [77 FR 24885] (HM–218G); however, PHMSA did not receive any comments on the environmental assessment contained in that rulemaking. In addition, PHMSA sought comment from the following Federal Agencies and modal partners:

- Department of Defense
- Environmental Protection Agency
- Federal Aviation Administration
- Federal Motor Carrier Safety Administration
- Federal Railroad Administration

PHMSA did not receive any adverse comments on the amendments proposed in this NPRM from these Federal Agencies.

Conclusion

The proposed amendments are intended to update, clarify, or provide relief from certain existing regulatory requirements to promote safer transportation practices; eliminate unnecessary regulatory requirements; facilitate international commerce; and make these requirements easier to understand. These proposed amendments, if adopted, will foster a greater level of compliance with the HMR and thus the net environmental impact of this proposal will be slightly positive.

The provisions of this proposed rule build on current regulatory requirements to enhance the transportation safety and security of shipments of hazardous materials transported by highway, rail, aircraft and vessel, thereby reducing the risks of an accidental or intentional release of hazardous materials and consequent environmental damage. PHMSA believes that there are no non-negligible environmental impacts associated with this proposed rule.

PHMSA welcomes any views, data, or information related to environmental impacts that may result if the proposed requirements are adopted, as well as possible alternatives and their environmental impacts.

J. Privacy Act

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

K. Executive Order 13609 and International Trade Analysis

Under Executive Order 13609 (“Promoting International Regulatory Cooperation”), agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards in order to protect the safety of the American public, and we have assessed the effects of the proposed rule to ensure that it does not cause unnecessary obstacles to foreign trade. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

L. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.* specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standard bodies. This NPRM does not involve voluntary consensus standards.

List of Subjects

49 CFR Part 171

Definitions and abbreviations, Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Reporting and recordkeeping requirements, Training.

49 CFR Part 176

Hazardous materials transportation, Maritime carriers, Reporting and recordkeeping requirements.

49 CFR Part 178

Hazardous materials transportation, Incorporation by reference, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 180

Hazardous materials transportation, Motor carriers, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, we are proposing to amend 49 CFR chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410, section 4 (28 U.S.C. 2461 note); Pub. L. 104–121, sections 212–213; Pub. L. 104–134, section 31001; 49 CFR 1.81 and 1.97.

■ 2. In § 171.7:
■ a. Revise paragraphs (l)(1), (2), and (5);
■ b. Add paragraph (l)(12);
■ c. Revise paragraph (n)(7); and
■ d. Revise paragraph (o).

The revisions and additions read as follows:

§ 171.7 Reference material.

* * * * *

(l) * * *

(1) Chlorine Institute Emergency Kit "A" for 100-lb. & 150-lb. Chlorine Cylinders (with the exception of repair method using Device 8 for side leaks), Edition 12, January 2013, into § 173.3.

(2) Chlorine Institute Emergency Kit "B" for Chlorine Ton Containers (with the exception of repair method using Device 9 for side leaks), Edition 10, January 2009, into § 173.3.

* * * * *

(5) Section 3, Pamphlet 57, Emergency Shut-Off Systems for Bulk Transfer of Chlorine, Edition 5, Revision 1, March 2009, into § 177.840.

* * * * *

(12) Sections 4 through 6, Pamphlet 168, Guidelines for Dual Valve Systems for Bulk Chlorine Transport, Edition 1, February 2013, into § 178.337–9.

* * * * *

(n) * * *

(7) CGA C–7–2014, Guide to Classification and Labeling of Compressed Gases, Tenth Edition, November 2014, into § 172.400a.

* * * * *

(o) *Department of Defense (DoD),* DoD Explosives Safety Board, 4800 Mark Center Drive, Suite 16E12, Alexandria, VA 22350, *https://www.ddesb.pentagon.mil/;* or Defense Logistics Agency, Technical and Quality Assurance Division, 8725 John J. Kingman Rd., Fort Belvoir, VA 22060, *http://www.dla.mil/Pages/default.aspx.*

(1) DOD TB 700–2; NAVSEAINST 8020.8C; TO 11A–1–47: Ammunition and Explosives Hazard Classification Procedures, July 30, 2012, into § 173.56.

(2) DOD DLAR 4145.41/AR 700–143/NAVSUPINST 4030.55D/AFMAN 24–210_IP/MCO 4030.40C: Packaging of Hazardous Material, April 21, 2015, into § 173.7.

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 3. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 4. In § 172.205, paragraph (j) is added to read as follows:

§ 172.205 Hazardous waste manifest.

* * * * *

(j) Electronic manifests that are obtained, completed, and transmitted in accordance with 40 CFR 262.20(a)(3), and used in accordance with § 262.24 in lieu of EPA Forms 8700–22 and 8700–22A are the legal equivalent of paper manifest forms bearing handwritten signatures, and satisfy for all purposes any requirements in these regulations to obtain, complete, sign, provide, use, or retain a manifest. Electronic signatures in conformance with 40 CFR 262.25 are therefore acceptable in lieu of handwritten signatures required by paragraphs (c) and (d) of this section provided one printed copy of the electronic manifest bearing the electronic signature is provided to the initial transporter as required by 40 CFR 262.24(d).

■ 5. In § 172.407, paragraphs (c) and (f) are revised to read as follows:

§ 172.407 Label specifications.

* * * * *

(c) *Size.* (1) Each diamond (square-on-point) label prescribed in this subpart must be at least 100 mm (3.9 inches) on each side with each side having a solid line inner border approximately 5 mm inside and parallel to the edge. The 5 mm measurement must be located from the outside edge of the label to the outside of the solid line forming the inner border. The width of the solid line forming the inner border must be at least 2 mm.

(i) If the size of the package so requires, the dimensions of the label and its features may be reduced provided the symbol and other elements of the label remain clearly visible. The solid line forming the inner border must remain approximately 5 mm from the outside edge of the label and the minimum width of the line must remain 2 mm.

(ii) Where dimensions are not specified, all features shall be in approximate proportion to those shown in §§ 172.411 through 172.448 of this subpart, as appropriate.

(iii) *Transitional exception*—A label in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue to be used until December 31, 2016.

(iv) For domestic transportation, a packaging labeled prior to January 1, 2017 and in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue in service until the end of its useful life.

(2) The CARGO AIRCRAFT ONLY label must be a rectangle measuring at least 110 mm (4.3 inches) in height by 120 mm (4.7 inches) in width. The words "CARGO AIRCRAFT ONLY" must be shown in letters measuring at least 6.3 mm (0.25 inches) in height.

(3) Except as otherwise provided in this subpart, the hazard class number, or division number, as appropriate, must be at least 6.3 mm (0.25 inches) and not greater than 12.7 mm (0.5 inches).

(4) When text indicating a hazard is displayed on a label, the label name must be shown in letters measuring at least 7.6 mm (0.3 inches) in height. For SPONTANEOUSLY COMBUSTIBLE or DANGEROUS WHEN WET labels, the words "Spontaneously" and "When Wet" must be shown in letters measuring at least 5.1 mm (0.2 inches) in height.

(5) The symbol on each label must be proportionate in size to that shown in the appropriate section of this subpart.

* * * * *

(f) *Exceptions.* Except for materials poisonous by inhalation (see § 171.8 of this chapter), a label conforming to specifications in the UN Recommendations, the ICAO Technical Instructions, the IMDG Code, or the Transport Canada TDG Regulations (IBR, see § 171.7 of this chapter) may be used in place of a corresponding label that conforms to the requirements of this subpart.

* * * * *

■ 6. In § 172.519, paragraphs (c) and (f) are revised to read as follows:

§ 172.519 General specifications for placards.

* * * * *

(c) *Size.* (1) Each diamond (square-on-point) placard prescribed in this subpart must measure at least 250 mm (9.84 inches) on each side and must have a solid line inner border approximately 12.5 mm inside and parallel to the edge. The 12.5 mm measurement is from the outside edge of the placard to the outside of the solid line forming the inner border.

(i) *Transitional exceptions.* A placard in conformance with the requirements of this paragraph in effect on December

31, 2014, may continue to be used until December 31, 2016.

(ii) For domestic transportation, a placard manufactured prior to January 1, 2017 in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue in service until the end of its useful life provided the color tolerances are maintained and are in accordance with the display requirements of this chapter.

(2) Except as otherwise provided in this subpart, the hazard class or division number, as appropriate, must be shown in numerals measuring at least 41 mm (1.6 inches) in height.

(3) Except as otherwise provided in this subpart, when text indicating a hazard is displayed on a placard, the printing must be in letters measuring at least 41 mm (1.6 inches) in height.

* * * * *

(f) *Exceptions.* When hazardous materials are offered for transportation or transported under the provisions of subpart C of part 171 of this chapter, a placard conforming to the specifications in the UN Recommendations, the ICAO Technical Instructions, the IMDG Code, or the Transport Canada TDG Regulations (IBR, see § 171.7 of this chapter) may be used in place of a corresponding placard conforming to the requirements of this subpart. However, a bulk packaging, transport vehicle, or freight container containing a material poisonous by inhalation (see § 171.8 of this chapter) must be placarded in accordance with this subpart (see § 171.23(b)(10) of this chapter).

* * * * *

■ 7. In § 172.604, paragraph (d) is revised to read as follows:

§ 172.604 Emergency response telephone number.

* * * * *

(d) The requirements of this section do not apply to—

(1) Hazardous materials that are offered for transportation under the provisions applicable to limited quantities or excepted quantities; or

(2) Materials properly described under the following shipping names:

Battery powered equipment.
Battery powered vehicle.
Carbon dioxide, solid.
Castor bean.
Castor flake.
Castor meal.
Castor pomace.
Consumer commodity.
Dry ice.
Engines, internal combustion.
Fish meal, stabilized.
Fish scrap, stabilized.
Krill Meal, PG III.
Refrigerating machine.
Vehicle, flammable gas powered.
Vehicle, flammable liquid powered.
Wheelchair, electric.

(3) Transportation vehicles or freight containers containing lading that has been fumigated and displaying the FUMIGANT marking (see § 172.302(g)) as required by § 173.9 of this chapter, unless other hazardous materials are present in the cargo transport unit.

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 8. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 9. In § 173.5a, paragraph (c)(1) is revised to read as follows:

§ 173.5a Oilfield service vehicles, mechanical displacement meter provers, and roadway striping vehicles exceptions.

* * * * *

(c) * * *

(1) *Authorized materials.* Only the hazardous materials listed in the table below may be transported in roadway striping vehicles. Cargo tanks may not be filled to a capacity that would be greater than liquid full at 130 °F.

HAZARDOUS MATERIALS DESCRIPTION

Proper shipping name	Hazard class/division	Identification No.	Packing group
Adhesives, *containing a flammable liquid*	3	UN1133	II
Paint *including paint, lacquer, enamel, stain, shellac solution, varnish, polish, liquid filler, and liquid lacquer base.*	3	UN1263	II
Paint related material *including paint thinning drying, removing, or reducing compound.*	3	UN1263	II
Flammable liquids, n.o.s.[a]	3	UN1993	II
Gasoline	3	UN1203	II
Acetone[b]	3	UN1090	II
Dichloromethane[b]	6.1	UN1593	III
Ethyl methyl ketone or Methyl ethyl ketone[b]	3	UN1193	II
Ethyl acetate[b]	3	UN1173	II
Methanol[b]	3	UN1230	II
Organic peroxide type E, liquid (Dibenzoyl peroxide)[c]	5.2	UN3107	NA
Petroleum distillates, n.o.s. *or* Petroleum products, n.o.s.[b]	3	UN1268	III
1,1,1-Trichloroethane[b]	6.1	UN2831	III
Toluene[b]	3	UN1294	II
Xylenes[b]	3	UN1307	II, III
Environmentally hazardous substance, liquid, n.o.s.[c]	9	UN3082	III
Corrosive liquid, basic, organic, n.o.s.[c]	8	UN3267	III
Corrosive liquids, n.o.s.[c]	8	UN1760	III
Elevated temperature liquid, n.o.s., *at or above 100 °C and below its flash point (including molten metals, molten salts, etc.)*[d]	9	UN3257	III
Amines, liquid, corrosive, n.o.s.[c] or Polyamines, liquid, corrosive, n.o.s.[c]	8	UN2735	III

[a]: Adhesive containing ethyl acetate.
[b]: Solvent.
[c]: Catalyst.
[d]: Thermoplastic material non-hazardous at room temperature.

* * * * *

■ 10. In § 173.24a, revise paragraphs (b)(1) and (3) to read as follows:

§ 173.24a Additional general requirements for non-bulk packagings and packages.

* * * * *

(b) * * *

(1) A single or composite non-bulk packaging may be filled with a liquid hazardous material only when the specific gravity of the material or gross mass of the package does not exceed that marked on the packaging, or a specific gravity of 1.2 if not marked, except as follows:

(i) A Packing Group I packaging may be used for a Packing Group II material with a specific gravity not exceeding the greater of 1.8, or 1.5 times the specific gravity or gross mass of the package marked on the packaging, provided all the performance criteria can still be met with the higher specific gravity material;

(ii) A Packing Group I packaging may be used for a Packing Group III material with a specific gravity not exceeding the greater of 2.7, or 2.25 times the specific gravity or gross mass of the package marked on the packaging, provided all the performance criteria can still be met with the higher specific gravity material; and

(iii) A Packing Group II packaging may be used for a Packing Group III material with a specific gravity not exceeding the greater of 1.8, or 1.5 times the specific gravity or gross mass of the package marked on the packaging, provided all the performance criteria can still be met with the higher specific gravity material.

* * * * *

(3) A single or composite non-bulk packaging which is tested and marked for liquid hazardous materials may be filled with a solid hazardous material to a gross mass, in kilograms, not exceeding the rated capacity of the packaging in liters, or gross mass of the package, multiplied by the specific gravity or gross mass of the package marked on the packaging, or 1.2 if not marked. In addition:

(i) A single or composite non-bulk packaging which is tested and marked for Packing Group I liquid hazardous materials may be filled with a solid Packing Group II hazardous material to a gross mass, in kilograms, not exceeding the rated capacity of the packaging in liters, or gross mass of the package, multiplied by 1.5, multiplied by the specific gravity or gross mass of the package marked on the packaging, or 1.2 if not marked.

(ii) A single or composite non-bulk packaging which is tested and marked for Packing Group I liquid hazardous materials may be filled with a solid Packing Group III hazardous material to a gross mass, in kilograms, not exceeding the rated capacity of the packaging in liters, or gross mass of the package, multiplied by 2.25, multiplied by the specific gravity or gross mass of the package marked on the packaging, or 1.2 if not marked.

(iii) A single or composite non-bulk packaging which is tested and marked for Packing Group II liquid hazardous materials may be filled with a solid Packing Group III hazardous material to a gross mass, in kilograms, not exceeding the rated capacity of the packaging in liters, or gross mass of the package, multiplied by 1.5, multiplied by the specific gravity or gross mass of the package marked on the packaging, or 1.2 if not marked.

* * * * *

■ 11. In § 173.31, paragraph (e) is revised to read as follows:

§ 173.31 Use of tank cars.

* * * * *

(e) *Special requirements for materials poisonous by inhalation*—(1) *Interior heater coils.* Tank cars used for materials poisonous by inhalation may not have interior heater coils.

(2) *Tank car specifications.* A tank car used for a material poisonous by inhalation must have a tank test pressure of 20.7 Bar (300 psig) or greater, head protection, and a metal jacket (*e.g.*, DOT 105S300W), except that—

(i) A higher test pressure is required if otherwise specified in this chapter; and

(ii) Each tank car constructed on or after March 16, 2009, and used for the transportation of PIH materials must meet the applicable authorized tank car specifications and standards listed in § 173.244(a)(2) or (3) and § 173.314(c) or (d).

(iii) [Reserved]

(iv) A tank car owner retiring or otherwise removing a tank car from service transporting materials poisonous by inhalation, other than because of damage to the car, must retire or remove cars constructed of non-normalized steel in the head or shell before removing any car in service transporting materials poisonous by inhalation constructed of normalized steel meeting the applicable DOT specification.

* * * * *

■ 12. In § 173.150, paragraph (g) is revised to read as follows:

§ 173.150 Exceptions for Class 3 (flammable and combustible liquids).

* * * * *

(g) *Limited quantities of retail products containing ethyl alcohol.* (1) Beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol classed as a flammable liquid or flammable solid containing not more than 70% ethyl alcohol by volume for liquids, by weight for solids are excepted from the HMR provided that:

(i) For non-glass inner packagings:

(A) The volume does not exceed 16 fluid ounces (473 mL) in capacity for liquids; or

(B) For volumes greater than 16 fluid ounces (473 mL) but not exceeding 1 gallon (5 L) the company name and the words "Contains Ethyl Alcohol" are marked on the package;

(C) Solids containing ethyl alcohol may be packaged in non-glass inner packagings not exceeding 1 pounds (.45 kg) capacity;

(D) For weight greater than 1 pounds (.45 kg) up to 8 pounds (3.6 kg) the company name and the words "Contains Ethyl Alcohol" are marked on the package.

(ii) For glass inner packagings:

(A) The volume does not exceed 8 fluid ounces (236 mL) in capacity; or

(B) For volumes greater than 8 fluid ounces (236 mL) to 16 fluid ounces (473 mL) the company name and the words "Contains Ethyl Alcohol" are marked on the package;

(C) Solids containing ethyl alcohol may be packaged in glass inner packagings not exceeding ½ pounds (.23 kg);

(D) For weight greater than ½ pound (.23 kg) up to 1 pounds (.45 kg) the company name and the words "Contains Ethyl Alcohol" are marked on the package.

(iii) The net liquid contents of all inner packagings in any single outer packaging may not exceed 192 fluid ounces (5.6 liters). The net solid contents of all inner packagings in any single outer packaging may not exceed 32 pounds (14.5 kg). The gross weight of any single outer package shipped may not exceed 65 pounds (29.4 kg); Inner packagings must be secured and cushioned within the outer package to prevent breakage, leakage, and movement.

(2) Beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol classed as a flammable liquid or flammable solid containing more than 70% ethyl alcohol by volume, by weight for solids are excepted from the HMR provided that:

(i) For inner packagings containing liquids the volume does not exceed 8 fluid ounces (250 mL) in capacity;

(ii) Solids containing ethyl alcohol are not packed in inner packagings exceeding ½ pound (0.23 kg) in weight;

(iii) The net liquid contents of all inner packagings in any single outer packaging may not exceed 192 fluid ounces (5.6 liters). The net solid contents of all inner packagings in any single outer packaging may not exceed 32 pounds (14.5 kg). The gross weight of any single outer package shipped may not exceed 65 pounds (29.4 kg). Inner packagings must be secured and cushioned within the outer package to prevent breakage, leakage, and movement.

(3) For transportation by passenger or cargo aircraft, no outer package may be transported which contains an inner packaging exceeding:

(i) 16 fluid ounces (473 mL) of flammable liquid; or

(ii) 1 pound (0.45 kg) of solids containing flammable liquid.

* * * * *

■ 13. In § 173.156, paragraph (b) is revised to read as follows:

§ 173.156 Exceptions for limited quantity and ORM.

* * * * *

(b) Packagings for limited quantity and ORM–D are specified according to hazard class in §§ 173.150 through 173.155, 173.306 and 173.309(b). In addition to exceptions provided for limited quantity and ORM–D materials elsewhere in this part, the following are provided:

(1) Strong outer packagings as specified in this part, marking requirements specified in subpart D of part 172 of this chapter, and the 30 kg (66 pounds) gross weight limitation when—

(i) Unitized in cages, carts, boxes or similar overpacks;

(ii) Offered for transportation or transported by:

(A) Rail;

(B) Private or contract motor carrier; or

(C) Common carrier in a vehicle under exclusive use for such service; and

(iii) Transported to or from a manufacturer, a distribution center, or a retail outlet, or transported to a disposal facility from one offeror.

(2) The 30 kg (66 pounds) gross weight limitation does not apply to packages of limited quantity materials marked in accordance with § 172.315 of this chapter, or, until December 31, 2020, materials classed and marked as ORM–D and described as a Consumer commodity, as defined in § 171.8 of this chapter, when offered for transportation or transported by highway or rail between a manufacturer, a distribution center, and a retail outlet provided—

(i) Inner packagings conform to the quantity limits for inner packagings specified in §§ 173.150(b), 173.152(b), 173.154(b), 173.155(b), 173.306(a) and (b), and 173.309(b), as appropriate;

(ii) The inner packagings are packed into corrugated fiberboard trays to prevent them from moving freely;

(iii) The trays are placed in a fiberboard box which is banded and secured to a metal, plastic, composite, or wooden pallet by metal, fabric, or plastic straps, to form a single palletized unit;

(iv) The package conforms to the general packaging requirements of subpart B of this part; and

(v) The maximum net quantity of hazardous material permitted on one palletized unit is 250 kg (550 pounds).

* * * * *

■ 14. In § 173.301, paragraphs (a)(11) and (12) are added to read as follows:

§ 173.301 General requirements for shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles and spherical pressure vessels.

* * * * *

(a) * * *

(11) Cylinder valves manufactured on or after May 4, 2015, used on cylinders to transport compressed gases must conform to the requirements in CGA V–9–2012. A valve for a UN pressure receptacle must conform to the requirements of § 173.301b(c)(1).

(12) Cylinder valve protection caps manufactured on or after May 4, 2015, must conform to the requirements of CGA V–9–2012. Cylinder valve protection caps used on UN cylinders must conform to the requirements in § 173.301b(c)(2)(ii).

* * * * *

PART 176—CARRIAGE BY VESSEL

■ 15. The authority citation for part 176 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 16. In § 176.415, paragraph (b)(5) is added to read as follows:

§ 176.415 Permit requirements for Division 1.5, ammonium nitrates, and certain ammonium nitrate fertilizers.

* * * * *

(b) * * *

(5) Ammonium nitrate, Division 5.1 (oxidizer) UN1942, shipped as a limited quantity, if the nearest COTP is notified at least 24 hours in advance of any loading or unloading in excess of 454 kg (1,000 pounds).

* * * * *

PART 178—SPECIFICATIONS FOR PACKAGINGS

■ 17. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 18. In § 178.35, paragraph (f)(7) is added to read as follows:

§ 178.35 General requirements for specification cylinders.

* * * * *

(f) * * *

(7) *Marking exceptions.* A DOT 4 or 4AL cylinder is not required to be marked with the service pressure.

* * * * *

■ 19. In § 178.337–9, paragraph (b)(8) is revised as follows:

§ 178.337–9 Pressure relief devices, piping, valves, hoses and fittings.

* * * * *

(b) * * *

(8) *Chlorine cargo tanks.* Angle valves on cargo tanks intended for chlorine service must conform to the standards of the Chlorine Institute, Inc., Dwg. 104–8 or "Section 3, Pamphlet 166, Angle Valve Guidelines for Chlorine Bulk Transportation" or "Sections 4 through 6, Pamphlet 168, Guidelines for Dual Valve Systems for Bulk Chlorine Transport, Edition 1, February 2013" (IBR, see § 171.7 of this chapter). Before installation, each angle valve must be tested for leakage at not less than 225 psig using dry air or inert gas.

■ 20. In § 178.516, paragraph (b)(7) is revised to read as follows:

§ 178.516 Standards for fiberboard boxes.

* * * * *

(b) * * *

(7) Authorization to manufacture, mark, and sell UN4G combination packagings with outer fiberboard boxes and with inner fiberboard components that have individual containerboard or paper wall basis weights that vary by not more than plus or minus 10% from the nominal basis weight reported in the initial design qualification test report.

■ 21. In § 178.703, paragraph (b)(6) is revised to as follows:

§ 178.703 Marking of IBCs.

* * * * *

(b) * * *

(6) For each composite IBC, the inner receptacle must be marked with at least the following information:

(i) The code number designating the IBC design type, the name and address or symbol of the manufacturer, the date of manufacture and the country authorizing the allocation of the mark as specified in paragraph (a) of this section. The date of manufacture of the inner receptacle may be different from the marked date of manufacture required by § 178.703(a)(1)(iv) or by § 180.352(d)(1)(iv) of this chapter provided that the retest and inspection of the IBCs be based on the earliest marked date; and

(ii) When a composite IBC is designed in such a manner that the outer casing is intended to be dismantled for transport when empty (such as, for the return of the IBC for reuse to the original consignor), each of the parts intended to be detached when so dismantled must be marked with the month and year of manufacture and the name or symbol of the manufacturer.

* * * * *

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

■ 22. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 23. In § 180.407, paragraph (g)(1)(iv) is revised to read as follows:

§ 180.407 Requirements for test and inspection of specification cargo tanks.

* * * * *

(g) * * *

(1) * * *

(iv) Each cargo tank must be tested hydrostatically or pneumatically to the internal pressure specified in the following table. At no time during the pressure test may a cargo tank be subject to pressures that exceed those identified in the following table:

Specification	Test pressure
MC 300, 301, 302, 303, 305, 306	The test pressure on the name plate or specification plate, 20.7 kPa (3 psig) or design pressure, whichever is greater.
MC 304, 307	The test pressure on the name plate or specification plate, 275.8 kPa (40 psig) or 1.5 times the design pressure, whichever is greater.
MC 310, 311, 312	The test pressure on the name plate or specification plate, 20.7 kPa (3 psig) or 1.5 times the design pressure, whichever is greater.
MC 330, 331	The test pressure on the name plate or specification plate, 1.5 times either the MAWP or the re-rated pressure, whichever is applicable.
MC 338	The test pressure on the name plate or specification plate, 1.25 times either the MAWP or the re-rated pressure, whichever is applicable.
DOT 406	The test pressure on the name plate or specification plate, 34.5 kPa (5 psig) or 1.5 times the MAWP, whichever is greater.
DOT 407	The test pressure on the name plate or specification plate, 275.8 kPa (40 psig) or 1.5 times the MAWP, whichever is greater.
DOT 412	The test pressure on the name plate or specification plate, 1.5 times the MAWP.

* * * * *

■ 24. In § 180.605, paragraph (l) is revised to read as follows:

§ 180.605 Requirements for periodic testing, inspection and repair of portable tanks.

* * * * *

(l) *Record retention.* (1) The owner of each portable tank or his authorized agent shall retain a written record of the date and results of all required inspections and tests, including an ASME manufacturer's date report, if applicable, and the name and address of the person performing the inspection or test, in accordance with the applicable specification. The manufacturer's data report, including a certificate(s) signed by the manufacturer, and the authorized design approval agency, as applicable, indicating compliance with the applicable specification of the portable tank, and related papers certifying that the portable tank was manufactured and tested in accordance with the applicable specification must be retained in the files of the owner, or his authorized agent, during the time that such portable tank is used for such service, except for Specifications 56 and 57 portable tanks.

(2) If the owner does not have the manufacturer's certificate required by the specification and the manufacturer's data report required by the ASME, the owner may contact the National Board for a copy of the manufacturer's data report, if the portable tank was registered with the National Board, or copy the information contained on the portable tanks specification plate and ASME Code data plates.

Issued in Washington, DC, on June 23, 2016, under authority delegated in 49 CFR 1.97.

William Schoonover,

Acting Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2016–15303 Filed 6–29–16; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160302174–6174–01]

RIN 0648–BF81

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Dolphin and Wahoo Fishery Off the Atlantic States; Regulatory Amendment 1

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement Regulatory Amendment 1 for the Fishery Management Plan (FMP) for the Dolphin and Wahoo Fishery off the Atlantic States (Regulatory Amendment 1) as prepared and submitted by the South Atlantic Fishery Management Council (Council). If implemented, this proposed rule would establish a commercial trip limit for Atlantic dolphin for vessels with a Federal commercial permit for Atlantic dolphin and wahoo. The purpose of this

proposed rule is to reduce the chance of an in-season closure of the dolphin commercial sector as a result of the annual catch limit (ACL) being reached during the fishing year and to reduce the severity of social impacts caused by these closures.

DATES: Written comments must be received on or before August 1, 2016.

ADDRESSES: You may submit comments on the proposed rule, identified by "NOAA–NMFS–2016–0033" by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0033,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Karla Gore, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in required fields if you wish to remain anonymous).

Electronic copies of Regulatory Amendment 1, which includes an environmental assessment, an assessment under the Regulatory Flexibility Act, a regulatory impact review, and fishery impact statement, may be obtained from *www.regulations.gov* or the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/s_atl/dw/2016/reg_am1/documents/pdfs/dw_reg_am1.pdf.*

FOR FURTHER INFORMATION CONTACT: Karla Gore, NMFS SERO, telephone: 727–551–5753, or email: *karla.gore@noaa.gov.*

SUPPLEMENTARY INFORMATION: The dolphin and wahoo fishery of the Atlantic is managed under the FMP. The FMP was prepared by the Council and implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Steven Act).

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the optimum yield from federally managed fish stocks. These mandates are intended to ensure that fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, while also protecting marine ecosystems.

In 2015, the commercial sector for Atlantic dolphin was closed on June 30, 2015 (80 FR 36932, June 29, 2015), as a result of the commercial ACL being met, thereby triggering accountability measures (AMs) and closing the sector. This was the first time the dolphin commercial fishing season was closed as a result of AMs in the history of management of Atlantic dolphin under the FMP. Regulatory Amendment 1 and this proposed rule would establish a commercial trip limit for Atlantic dolphin once 75 percent of the commercial ACL is met. The dolphin commercial ACL had already been increased from 1,157,001 lb (524,807 kg), round weight, to 1,534,485 lb (696,031 kg), round weight, by the final rule for Amendment 8 to the FMP (81 FR 3781, January 22, 2016). The Council has determined that this proposed action would reduce the severity of social impacts of an AM closure of the dolphin commercial sector by increasing the likelihood that the commercial sector will remain open throughout the fishing year.

Management Measures Contained in This Proposed Rule

This proposed rule would establish a commercial trip limit for dolphin for vessels that have a Federal commercial permit for Atlantic dolphin and wahoo.

Dolphin Commercial Trip Limit

Currently, no commercial trip limit exists for vessels that possess a Federal commercial permit for Atlantic dolphin and wahoo. However, there is a commercial trip limit of 200 lb (91 kg) of dolphin and wahoo, combined, for vessels that do not have a Federal commercial permit for Atlantic dolphin and wahoo but do have a Federal commercial permit in any other fishery, provided that all fishing and landings from that trip occur north of 39° N. lat. (50 CFR 622.278(a)(2)). This proposed rule would establish a commercial trip limit of 4,000 lb (1,814 kg), round weight, for the dolphin commercial sector in the Atlantic, once 75 percent of the commercial ACL is reached. This trip limit would apply to vessels that have a Federal commercial permit for Atlantic dolphin and wahoo, provided that the vessel is not operating a charter vessel or headboat. There would be no applicable trip limit for the dolphin commercial sector in the Atlantic prior to 75 percent of the commercial ACL being reached. The Council determined that establishing this commercial trip limit would reduce the chances of early closures during the fishing year as a result of AMs being triggered, and thereby reduce the severity of any socioeconomic impacts as a result of a commercial sector closure.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with Regulatory Amendment 1, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

A description of this proposed rule, why it is being considered, the objectives of, and legal basis for this proposed rule are contained in the preamble and in the **SUMMARY** section of the preamble of this proposed rule. The Magnuson-Stevens Act provides the basis for this proposed rule.

This proposed rule is expected to directly affect federally permitted Atlantic dolphin and wahoo commercial fishermen fishing for dolphin in the South Atlantic and northeastern states (states north of North Carolina) (Atlantic). The Small Business Administration established size criteria for all major industry sectors in the U.S. including fish harvesters. A business involved in fish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts are not in excess of $20.5 million (NAICS code 114111, finfish fishing) for all of its affiliated operations worldwide.

From 2010 through 2014, an average of 531 vessels with the Federal commercial permit for Atlantic dolphin and wahoo that landed at least 1 lb (0.45 kg) of dolphin generated total combined revenues (2014 dollars) of approximately $600,000 from dolphin, $3.87 million from other species jointly landed with dolphin, and $15.40 million from all other species in trips where dolphin was not caught. The average annual revenue per vessel from all species, including dolphin, caught by these vessels was $37,303. Of the 531 vessels, an average of 23 vessels used longline for harvesting dolphin and generated combined total revenues (2014 dollars) of approximately $361,000 from dolphin, $1.37 million from other species jointly landed with dolphin, and $1.89 million from all other species in trips where dolphin was not caught. The average annual revenue per longline vessel was $82,276 (2014 dollars). Vessels that caught and landed dolphin may also operate in other fisheries, the revenues of which are not known and are not reflected in these totals. Based on revenue information, all commercial vessels directly affected by this proposed rule may be assumed to be small entities.

Because all entities expected to be directly affected by this proposed rule are assumed to be small entities, NMFS determined that this proposed rule would affect a substantial number of small entities. However, the issue of disproportionate effects on small versus large entities does not arise in the present case.

This proposed rule would establish a 4,000 lb (1,814 kg), round weight, commercial trip limit for dolphin for vessels with a Federal commercial permit for Atlantic dolphin and wahoo, once 75 percent of the commercial ACL is reached.

For the first time, the dolphin commercial sector was subject to an in-season closure on June 30, 2015, when the sector's ACL of 1,157,001 lb (524,806 kg), round weight, was reached (80 FR 36249, June 24, 2015, and 80 FR 36932, June 29, 2015). However, the recently implemented final rule for Amendment 8 to the FMP increased the dolphin commercial ACL from 1,157,001 lb (524,807 kg), round weight, to 1,534,485 lb (696,031 kg), round weight (81 FR 3781, January 22, 2016). Using 2015 data for the months open to commercial dolphin harvest during the fishing year and average 2010–2014 data for the months closed to dolphin harvest, NMFS estimated that in the absence of AM closures and commercial trip limits the 2015 commercial landings would have been approximately 1,229,669 lb (557,768 kg), round weight, with a dockside value of $3,725,896 (2014 dollars). Thus, if the increased dolphin commercial allocation had been in effect in 2015, it is likely that no commercial closure would have occurred.

Based on the increased commercial allocation, and assuming effort in 2016 and onwards would remain the same as estimated for the 2015 fishing year, 75 percent of the commercial ACL would be estimated to be reached on August 25 each year, and the proposed trip limit would then apply for the rest of the fishing year. The projected landings under this scenario would be 1,229,669 lb (557,768 kg), round weight, with a dockside value of $3,725,896 (2014 dollars). Thus, the proposed trip limit would not result in any reduction in total landings or revenues.

Although total landings or revenues would not be adversely affected, the proposed trip limit would be expected to have disproportionate impacts on vessels, with high-volume vessels such as those using longline gear more adversely affected than others. However, based on the estimated landings and effort distribution by gear type for 2015, the proposed trip limit would not be expected to adversely affect the trips and landings of any vessel regardless of the gear type they used.

Possibilities exist that the dolphin commercial sector may increase future effort and landings so that the total harvest could reach or exceed the commercial ACL if unrestrained by a trip limit. The harvest closure in 2015, even though it happened before the increase in the commercial ACL took effect, could motivate current participants to increase their effort to take advantage of fishing opportunities before harvest is prohibited. Because the Atlantic dolphin and wahoo commercial permit is an open access permit, new entrants, particularly longliners that fish for highly migratory species, could enter the dolphin and wahoo fishery and increase total effort and harvest. If this occurs, the proposed trip limits could constrain total harvest and prolong the commercial season. Total revenues for a fishing year would be expected to be higher, so long as the higher landings do not substantially depress the dockside price for dolphin. It cannot be determined, however, if higher revenues would translate to higher profits because the trip limit would reduce profit per trip. However, based on available data, NMFS analysis is that the proposed trip limit may be expected to have no adverse effects on vessel revenues, and thus, the proposed trip limit may be considered as a precautionary measure at this time and will not have a significant economic impact on the affected small entities.

No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, recordkeeping, or other compliance requirements are introduced by this proposed rule. Accordingly, this rule does not implicate the Paperwork Reduction Act.

The information provided above supports a determination that this rule would not have a significant economic impact on a substantial number of small entities. Because this rule, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Commercial, Dolphin, Fisheries, Fishing, Trip limits.

Dated: June 23, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, NMFS proposes to amend 50 CFR part 622 as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.278, revise paragraph (a) to read as follows:

§ 622.278 Commercial trip limits.

* * * * *

(a) *Trip-limited permits*—(1) *Atlantic wahoo.* (i) The trip limit for wahoo in or from the Atlantic EEZ is 500 lb (227 kg). This trip limit applies to a vessel that has a Federal commercial permit for Atlantic dolphin and wahoo, provided that the vessel is not operating as a charter vessel or headboat.

(ii) See § 622.280(b)(1) for the limitations regarding wahoo after the ACL is reached.

(2) The trip limit for a vessel that does not have a Federal commercial vessel permit for Atlantic dolphin and wahoo but has a Federal commercial vessel permit in any other fishery is 200 lb (91 kg) of dolphin and wahoo, combined, provided that all fishing on and landings from that trip are north of 39° N. lat. (A charter vessel/headboat permit is not a commercial vessel permit.)

(3) *Atlantic dolphin.* (i) Once 75 percent of the ACL specified in

§ 622.280(a)(1)(i) is reached, the trip limit is 4,000 lb (1,814 kg), round weight. When the conditions in this paragraph (a)(3)(i) have been met, the Assistant Administrator will implement this trip limit by filing a notification with the Office of the Federal Register. This trip limit applies to a vessel that has a Federal commercial permit for Atlantic dolphin and wahoo, provided that the vessel is not operating as a charter vessel or headboat.

(ii) See § 622.280(a)(1) for the limitations regarding dolphin after the ACL is reached.

* * * * *

[FR Doc. 2016–15494 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 81, No. 126
Thursday, June 30, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0042]

National Wildlife Services Advisory Committee; Reestablishment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to reestablish.

SUMMARY: Pursuant to the Federal Advisory Committee Act, we are giving notice that the Secretary of Agriculture intends to reestablish the National Wildlife Services Advisory Committee for a 2-year period. The Secretary has determined that the Committee is necessary and in the public interest.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Joyce, Designated Federal Officer, Wildlife Services, APHIS, 4700 River Road, Unit 87, Riverdale, MD 20737; (301) 851–3999.

SUPPLEMENTARY INFORMATION: The purpose of the National Wildlife Services Advisory Committee (the Committee) is to advise the Secretary of Agriculture on policies, program issues, and research needed to conduct the Wildlife Services program. The Committee also serves as a public forum enabling those affected by the Wildlife Services program to have a voice in the program's policies.

Done in Washington, DC, this 24th day of June 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–15551 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2016–0023]

Codex Alimentarius Commission: Meeting of the Codex Committee on Processed Fruits and Vegetables

AGENCY: Office of the Deputy Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Deputy Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Agricultural Marketing Service (AMS), are sponsoring a public meeting on August 1, 2016. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 28th Session of the Codex Committee on Processed Fruits and Vegetables (CCPFV) of the Codex Alimentarius Commission (Codex), taking place in Washington, DC, September 12–16, 2016. The Deputy Under Secretary for Food Safety and the AMS recognize the importance of providing interested parties the opportunity to obtain background information on the 28th Session of the CCPFV and to address items on the agenda.

DATES: The public meeting is scheduled for Monday, August 1, 2016, from 1:00 p.m.–4:00 p.m.

ADDRESSES: The public meeting will take place at the USDA, Jamie L. Whitten Building, 1400 Independence Avenue SW., Room 107–A, Washington, DC 20250.

Documents related to the 28th Session of the CCPFV will be accessible via the Internet at the following address: *http://www.codexalimentarius.org/meetings-reports/en/.*

Dorian LaFond, U.S. Delegate to the 28th Session of the CCPFV, invites U.S. interested parties to submit their comments electronically to the following email address: *Dorian.Lafond@usda.gov.*

Call-In-Number:

If you wish to participate in the public meeting for the 28th Session of the CCPFV by conference call, please use the following call-in-number.

Call-in-Number: 1–888–844–9904

The participant code will be posted on the following Web page: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/public-meetings*

Registration:

Attendees may register to attend the public meeting by emailing *uscodex@fsis.usda.gov* by July 27,2016. Early registration is encouraged as it will expedite entry into the building. The meeting will be held in a Federal building. Attendees should bring photo identification and plan for adequate time to pass through security screening systems. Attendees who are not able to attend the meeting in person, but who wish to participate, may do so by phone.

FOR FURTHER INFORMATION ABOUT THE 28TH SESSION OF THE CCPFV CONTACT: Dorian LaFond, Agricultural Marketing Service, Fruits and Vegetables Division, Mail Stop 0235, Room 2086, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250–0235, Telephone: (202) 690–4944, Fax: (202) 720–0016, Email: *Dorian.Lafond@usda.gov.*

FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT: Doreen Chen-Moulec, U.S. Codex Office, 1400 Independence Avenue SW., South Agriculture Building, Room 4865, Washington, DC 20250. Telephone: (202) 205–7760, Fax: (202) 720–3157, Email: *Doreen.Chen-Moulec@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The CCPFV is responsible for elaborating worldwide standards and related texts for all types of processed fruits and vegetables including, but not limited to canned, dried, and frozen products, as well as fruit and vegetable juices and nectars.

The Committee is hosted by the United States.

Issues To Be Discussed at the Public Meeting

The following items on the Agenda for the 28th Session of the CCPFV will be discussed during the public meeting:

- Matters referred to the Committee by Codex and its subsidiary bodies;
- Proposed draft Annex on canned pineapples (for inclusion in the Standard for Certain Canned Fruits (CODEX STAN 319–2015) (Step 4);
- Proposed draft Annexes on quick frozen vegetables (for inclusion in the Standard for Quick Frozen Vegetables (CODEX STAN 320–2015) (Step 4) and methods of analysis for quick frozen vegetables (for inclusion in Section 11—Methods of Analysis and Sampling of CODEX STAN 320–2015);
- Discussion paper on standardization of dry and dried produce;
- Food additive provisions in Codex standards for processed fruits and vegetables (canned chestnuts and canned chestnut puree and pickled fruits and vegetables); and
- Status of work on the revision of Codex standards for processed fruits and vegetables.

Each issue listed will be fully described in documents distributed, or to be distributed, by the Secretariat before the Meeting. Members of the public may access or request copies of these documents (see **ADDRESSES**).

Public Meeting

At the August 1, 2016, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate for the 28th Session of the CCPFV, Dorian LaFond (see **ADDRESSES**). Written comments should state that they relate to the activities of the 28th Session of the CCPFV.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register* .

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe*. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf*, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410.

Fax: (202) 690–7442.

E-mail: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on June 27, 2016.

Paulo Almeida,

Acting U.S. Manager for Codex Alimentarius.

[FR Doc. 2016–15599 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2016–0022]

National Advisory Committee on Meat and Poultry Inspection

AGENCY: Food Safety and Inspection Service, Department of Agriculture.

ACTION: Notice of the Renewal of the U.S. Department of Agriculture National Advisory Committee on Meat and Poultry Inspection.

SUMMARY: The U.S. Department of Agriculture intends to renew the National Advisory Committee on Meat and Poultry Inspection (NACMPI). The purpose of the Committee is to provide advice to the Secretary of Agriculture concerning State and Federal programs with respect to meat, poultry and processed egg products inspection, food safety, and other matters that fall within the scope of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).

For Further Information about the NACMPI Contact: Ms. Natasha Williams, Program Specialist, Designated Federal Officer, Outreach and Partnership Division, Office of Outreach, Employee Education and Training, Food Safety and Inspection Service, Patriot Plaza III Building, 355 E Street SW., Washington, DC 20024; Telephone: (202) 690–6531; Fax: (202) 690–6519; Email: *Natasha.Williams@fsis.usda.gov*

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.), notice is hereby given that the Secretary of Agriculture intends to renew the NACMPI for two years. The Committee provides advice and recommendations to the Secretary on meat and poultry inspection programs, pursuant to sections 7(c), 24, 301(a)(3), and 301(c) of the Federal Meat Inspection Act, 21 U.S.C. 607(c), 624, 645, 661(a)(3), and 661(c), and to sections 5(a)(3), 5(c), 8(b), and 11(e) of the Poultry Products Inspection Act, 21 U.S.C. 454(a)(3), 454(c), 457(b), and 460(e).

A copy of the current charter and other information about the committee can be found at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/advisory-committees/nacmpi.*

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register*. FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe*. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf*, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, Fax: (202) 690–7442, Email: *program.intake@usda.gov*.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on June 27, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016–15550 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2016–0012]

International Standard-Setting Activities

AGENCY: Office of Food Safety, USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the sanitary and phytosanitary standard-setting activities of the Codex Alimentarius Commission (Codex), in accordance with section 491 of the Trade Agreements Act of 1979, as amended, and the Uruguay Round Agreements Act. This notice also provides a list of other standard-setting activities of Codex, including commodity standards, guidelines, codes of practice, and revised texts. This notice, which covers Codex activities during the time periods from June 1, 2015, to May 31, 2016, and June 1, 2016, to May 31, 2017, seeks comments on standards under consideration and recommendations for new standards.

ADDRESSES: FSIS invites interested persons to submit their comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov*. Follow the on-line instructions at the Web site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Mail to the U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163B, Washington, DC 20250–3700.
- *Hand- or courier-delivered items:* Deliver to OPPD, RIMS, Docket Clearance Unit, Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700.

Instructions: All items submitted by mail or email are to include the Agency name and docket number FSIS–2016–0012. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to *http://www.regulations.gov*.

Please state that your comments refer to Codex and, if your comments relate to specific Codex committees, please identify the committee(s) in your comments and submit a copy of your comments to the delegate from that particular committee.

Docket: For access to background documents or comments received, visit the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700, between 8:00 a.m. and 4:30 p.m., Monday through Friday. A complete list of U.S. delegates and alternate delegates can be found in Attachment 2 of this notice.

FOR FURTHER INFORMATION CONTACT: Mary Frances Lowe, United States Manager for Codex Alimentarius, U.S. Department of Agriculture, Office of Food Safety, South Agriculture Building, 1400 Independence Avenue SW., Room 4861, Washington, DC 20250–3700; Telephone: (202) 205–7760; Fax: (202) 720–3157; Email: *USCodex@fsis.usda.gov*.

For information pertaining to particular committees, contact the delegate of that committee. Documents pertaining to Codex and specific committee agendas are accessible via the Internet at *http://www.codexalimentarius.org/meetings-reports/en/*. The U.S. Codex Office also maintains a Web site at *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius*.

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established on January 1, 1995, as the common international institutional framework for the conduct of trade relations among its members in matters related to the Uruguay Round Trade Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade (GATT). United States membership in the WTO was approved and the Uruguay Round Agreements Act (Uruguay Round Agreements) was signed into law by the President on December 8, 1994, Public Law 103–465, 108 Stat. 4809. The Uruguay Round Agreements became effective, with respect to the United States, on January 1, 1995. The Uruguay Round Agreements amended the Trade Agreements Act of 1979. Pursuant to section 491 of the Trade Agreements Act of 1979, as amended, the President is required to designate an agency to be "responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization" (19 U.S.C. 2578). The main international standard-setting organizations are Codex, the World Organisation for Animal Health, and the International Plant Protection Convention. The President, pursuant to Proclamation No. 6780 of March 23, 1995, (60 FR 15845), designated the U.S. Department of Agriculture as the agency responsible for informing the public of the SPS standard-setting activities of each international standard-setting organization. The Secretary of Agriculture has delegated to the Office of Food Safety the responsibility to inform the public of the SPS standard-setting activities of Codex. The Office of Food Safety has, in turn, assigned the responsibility for informing the public of the SPS standard-setting activities of Codex to the U.S. Codex Office (USCO).

Codex was created in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the principal international organization for establishing standards for food. Through adoption of food standards, codes of practice, and other guidelines developed by its committees and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers, ensure fair practices in the food trade, and promote coordination of food standards work undertaken by international governmental and nongovernmental organizations. In the United States, U.S. Codex activities are managed and carried out by the United States Department of Agriculture (USDA); the Food and Drug Administration (FDA), Department of Health and Human Services (HHS); the National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC); and the Environmental Protection Agency (EPA).

As the agency responsible for informing the public of the SPS standard-setting activities of Codex, the Office of Food Safety publishes this notice in the **Federal Register** annually. Attachment 1 (Sanitary and Phytosanitary Activities of Codex) sets forth the following information:

1. The SPS standards under consideration or planned for consideration; and

2. For each SPS standard specified:

a. A description of the consideration or planned consideration of the standard;

b. Whether the United States is participating or plans to participate in the consideration of the standard;

c. The agenda for United States participation, if any; and

d. The agency responsible for representing the United States with respect to the standard.

TO OBTAIN COPIES OF THE STANDARDS LISTED IN ATTACHMENT 1, PLEASE CONTACT THE CODEX DELEGATE OR THE U.S. CODEX OFFICE.

This notice also solicits public comment on standards that are currently under consideration or planned for consideration and recommendations for new standards. The delegate, in conjunction with the responsible agency, will take the comments received into account in participating in the consideration of the standards and in proposing matters to be considered by Codex.

The U.S. delegate will facilitate public participation in the United States Government's activities relating to Codex. The U.S. delegate will maintain a list of individuals, groups, and organizations that have expressed an interest in the activities of the Codex Committees and will disseminate information regarding U.S. delegation activities to interested parties. This information will include the status of each agenda item; the U.S. Government's position or preliminary position on the agenda items; and the time and place of planning meetings and debriefing meetings following the Codex committee sessions. In addition, the U.S. Codex Office makes much of the same information available through its Web page at *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius.* If you would like to access or receive information about specific committees, please visit the Web page or notify the appropriate U.S. delegate or the U.S. Codex Office, Room 4861, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250–3700 (*uscodex@fsis.usda.gov*).

The information provided in Attachment 1 describes the status of Codex standard-setting activities by the Codex Committees for the time periods from June 1, 2015, to May 31, 2016, and June 1, 2016, to May 31, 2017. Attachment 2 provides a list of U.S. Codex Officials (including U.S. delegates and alternate delegates). A list of forthcoming Codex sessions may be found at: *http://www.codexalimentarius.org/meetings-reports/en/.*

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on: June 27, 2016.

Paulo Almeida,

Acting U.S. Manager for Codex Alimentarius.

Attachment 1

Sanitary and Phytosanitary Activities of Codex

Codex Alimentarius Commission and Executive Committee

The Codex Alimentarius Commission will convene for its 39th Session June 27–July 1, 2016, in Rome, Italy. At that time, it will consider proposals for new work as well as proposed standards, codes of practice, and related matters forwarded to the Commission by the general subject committees, commodity committees, and regional coordinating committees for adoption as Codex standards and guidance. The Commission will also consider the relations between FAO and WHO policies, strategies and guidelines and Codex work; Codex work on antimicrobial resistance; FAO/WHO Scientific Support for Codex; and the FAO/WHO Project and Trust Fund for Enhanced Participation in Codex; and financial and budgetary issues.

Before the Commission meeting, the Executive Committee will meet at its 71st Session, June 20–23, 2016. It is composed of the chairperson; vice-chairpersons; seven members elected from the Commission from each of the following geographic regions: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, and South-West Pacific; and regional coordinators from the six regional committees. Canada is the elected representative from North America; the United States will participate as an advisor. The Executive Committee will conduct a critical review of the elaboration of Codex standards and will consider the implementation status of the Codex Strategic Plan (2014–2019), preparation for the 2020–2025 Strategic Plan, Codex work on antimicrobial resistance, Codex work management and functioning of the Executive Committee, scientific support for Codex work, issues related to committees working by correspondence, and financial and budgetary issues.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes.

Codex Committee on Residues of Veterinary Drugs in Foods

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) determines priorities for the consideration of residues of veterinary drugs in foods and recommends Maximum Residue Limits (MRLs) for veterinary drugs. The Committee also develops codes of practice, as may be required, and considers methods of sampling and analysis for the determination of veterinary drug residues in food. A veterinary drug is defined as any substance applied or administered to any food producing animal, such as meat or milk producing animals, poultry, fish, or bees, whether used for therapeutic, prophylactic or diagnostic purposes, or for modification of physiological functions or behavior.

A Codex Maximum Residue Limit (MRL) for residues of veterinary drugs is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be permitted or recognized as acceptable in or on a food. Residues of a veterinary drug include the parent compounds or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned. An MRL is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI) or on the basis of a temporary ADI that utilizes an additional safety factor. When establishing an MRL, consideration is also given to residues that occur in food of plant origin or the environment. Furthermore, the MRL may be reduced to be consistent with official recommended or authorized usage, approved by national authorities, of the veterinary drugs under practical conditions.

An ADI is an estimate made by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, which can be ingested daily in food over a lifetime without appreciable health risk.

The Committee will convene its 23rd Session in Houston, Texas, October 17–21, 2016. The Committee plans to discuss the following items:

- Matters of Interest arising from FAO/WHO and from the 81st Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA);
- Report of the World Organisation for Animal Health (OIE) activities, including the harmonization of technical requirements for registration of veterinary medicinal products;
- Proposed draft Risk Management Recommendation (RMR) for gentian violet at Step 3;
- Proposed draft MRLs for ivermectin (cattle muscle) and lasalocid sodium (chicken, turkey, quail and pheasant kidney, liver, muscle, skin + fat) at Step 4;
- Proposed draft MRLs for ivermectin (cattle fat, kidney, muscle), teflubenzuron (salmon fillet, muscle) and zilpaterol hydrocholoride (cattle fat, kidney, liver, muscle) at Step 3;
- Discussion paper on unintended presence of residues of veterinary drugs in food commodities resulting from the carry-over of drug residues into feed;
- Discussion paper on the establishment of a rating system to establish priority for CCRVDF work;
- Global survey to provide information to the CCRVDF to move compounds from the database on countries' needs for MRLs to the JECFA Priority List (Report of EWG);
- Draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA; and
- Other Business and Future Work.

Responsible Agencies: HHS/FDA/Center for Veterinary Medicine; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Contaminants in Foods

The Codex Committee on Contaminants in Foods (CCCF) establishes or endorses permitted maximum levels (MLs) or guideline levels for contaminants and naturally occurring toxicants in food and feed; prepares priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives; considers and elaborates methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed; considers and elaborates standards or codes of practice for related subjects; and considers other matters assigned to it by the Commission in relation to contaminants and naturally occurring toxicants in food and feed.

The Committee convened for its 10th Session in Rotterdam, The Netherlands, April 4–8, 2016. The relevant document is REP16/CF. The following items are to be considered for adoption by the 39th Session of the Commission in June 2016:

To be considered for adoption at Step 8:

- Draft ML for inorganic arsenic in husked rice; and
- Draft revised Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51–2003).

To be considered for adoption at Step 5/8:

- Proposed draft MLs for lead in fruit juices and nectars ready to drink (inclusion of passion fruit); canned fruits (inclusion of canned berries and other small fruits); canned vegetables (inclusion of canned leafy vegetables and canned legume vegetables); jams, jellies, and marmalades (lower ML and inclusion of marmalades); pickled cucumbers (lower ML); preserved tomatoes (lower ML and note on the application of a concentration factor); and table olives (lower ML); and
- Proposed draft annexes on zearalenone, fumonisins, ochratoxin A, trichothecenes and aflatoxins to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51–2003).

The Committee will continue working on:

- Proposed draft annex on ergot and ergot alkaloids in cereal grains (Annex to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51–2003);
- Outstanding issues related to the review of MLs for lead in selected fruits and vegetables (fresh and processed) and other selected food categories;
- Proposed draft Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice;
- Proposed draft MLs for cadmium in chocolate and cocoa-derived products;
- Proposed draft Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Spices and its annexes;

- Proposed draft MLs for total aflatoxins in ready to eat peanuts following the JECFA evaluation;
- Discussion paper on MLs for mycotoxins in spices;
- Discussion paper on methylmercury in tuna (fresh/frozen and canned) and in other fish species;
- Discussion paper on non-dioxin like PCBs in the Code of Practice for the Prevention and Reduction of Dioxins and Dioxin like PCB Contamination in Food and Feeds (CAC/RCP 62–2006);
- Pyrrolizidine Alkaloids following the outcome of the JECFA evaluation; and
- Priority list on contaminants and naturally occurring toxicants proposed for evaluation by JECFA.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Additives

The Codex Committee on Food Additives (CCFA) establishes or endorses acceptable maximum levels (MLs) for individual food additives; prepares a priority list of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); assigns functional classes to individual food additives; recommends specifications of identity and purity for food additives for adoption by the Codex Alimentarius Commission; considers methods of analysis for the determination of additives in food; and considers and elaborates standards or codes of practice for related subjects such as the labeling of food additives when sold as such. The 48th Session of the Committee convened in Xi'an, China, March 14–18, 2016. The relevant document is REP16/FA. Immediately prior to the Plenary Session, there was a two-day physical Working Group on the General Standard for Food Additives (GSFA) chaired by the United States.

The following items will be considered by the 39th Session of the Commission in June 2016:

To be considered for approval:

- Amendments to food additive provisions in commodity standards.

To be considered for adoption:

- Revised food additives section of the Standards for Cocoa Butter *(CODEX STAN 86–1981),* Chocolate and Chocolate Products *(CODEX STAN 87–1981),* Cocoa *(Cacao)* Mass *(Cocoa/Chocolate liquor)* and Cocoa Cake (CODEX STAN 141–1983) and Cocoa Powders *(Cocoas)* and Dry Mixtures of Cocoa and Sugars *(CODEX STAN 105–1981);*
- Revised food additive provisions of the GSFA related to the alignment of the four commodity standards for chocolate and chocolate products and the commodity standards identified by the Committee on Fish and Fishery Products (CCFFP); and
- Revised the food additive provision of the GSFA for benzoates in water-based flavored drinks in response to a recommendation from JECFA.

To be considered at Step 8 and 5/8:

- Draft and proposed draft food additive provisions of the GSFA.

To be considered at Step 5/8:

- Proposed draft specifications for the identity and purity of food additives;
- Proposed draft amendments to the *International Numbering System (INS) for Food Additives (CAC/GL 36–1989);*
- Proposed draft revision of food category 01.1 "Fluid milk and milk products" of the GSFA and consequential changes; and
- Proposed draft revision of Sections 4.1c and 5.1c of the *General Standard for the Labeling of Food Additives When Sold as Such (CODEX STAN 107–1981).*

The Committee will continue working on:

- Proposed draft food additive provisions of the GSFA (eWG led by the United States);
- Amendments to the INS for food additives; and
- *Specifications for the Identity and Purity of Food Additives* (82nd JECFA);
- Alignment of the food additive provisions of commodity standards and relevant provisions of the GSFA (eWG led by Australia and the United States);
- Recommendations on the use of food additives in wine and specific provisions for acidity regulators, stabilizers, and antioxidants (eWG led by France and Australia);
- Discussion paper on the management of CCFA work (China and United States);
- Discussion paper on the use of nitrates and nitrites (Netherlands);
- Proposal for additions and changes to the *Priority List of Substances Proposed for Evaluation* by JECFA;
- Information document on the GSFA; and
- Information document on food additive provisions in commodity standards.

The Committee also agreed to hold a physical Working Group on the GSFA immediately preceding the 49th Session of CCFA to be chaired by the United States. The group will discuss:

- The recommendations of the eWG on the GSFA on food additive provisions to be circulated for comment.
- The comments submitted in responses to a circular letter requesting information on the use and use levels of adipic acid.
- The new proposals and proposed revisions of food additive provisions in the GSFA.

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Pesticide Residues

The Codex Committee on Pesticide Residues (CCPR) is responsible for establishing maximum residue limits (MRLs) for pesticide residues in specific food items or in groups of food; establishing MRLs for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health; preparing priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR); considering methods of sampling and analysis for the determination of pesticide residues in food and feed; considering other matters in relation to the safety of food and feed containing pesticide residues; and establishing maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides in specific food items or groups of food.

The 48th Session of the Committee met in Chongqing, China, April 25–30, 2016. The relevant document is REP16/PR. The following items will be considered at the 39th Session of the Codex Alimentarius Commission in June 2016:

To be considered for adoption at Step 5/8:

- Proposed draft MRLs for pesticides

The Committee will continue working on:

- Draft MRLs for pesticides
- Proposed draft MRLs for pesticides
- Draft revision to the Classification of Food and Feed (vegetable commodity groups: Group 015—Pulses)
- Proposed draft revision to the Classification of Food and Feed (selected commodity groups Group 015—Grasses of Cereal grains)
- Proposed draft revision to the Classification of Food and Feed (other vegetable commodity groups: Group 014—Legume vegetables, Group 011—Fruiting vegetables, cucurbits)
- Proposed draft revision to the Classification of Food and Feed:

1. Group 021—Grasses for sugars or syrup production and;
2. Group 024—Seeds for beverages and sweets.

- Proposed draft tables on examples of selection of representative commodities (for inclusion in the principles and guidance for the selection of representative commodities for the extrapolation of maximum residue limits for pesticides for commodity groups)

- Proposed draft *Guidance on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues*
- Establishment of Codex schedules and priority list of pesticides for evaluation by JMPR
- Discussion paper on the possible revision of the International Estimated Short-Term Intake (IESTI) equations

Responsible Agencies: EPA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Methods of Analysis and Sampling

The Codex Committee on Methods of Analysis and Sampling (CCMAS) defines the criteria appropriate to Codex Methods of Analysis and Sampling; serves as a coordinating body for Codex with other international groups working on methods of analysis and sampling and quality assurance systems for laboratories; specifies, on the basis of final recommendations submitted to it by the bodies referred to above, reference methods of analysis and sampling appropriate to Codex standards which are generally applicable to a number of foods; considers, amends if necessary, and endorses as appropriate, methods of analysis and sampling proposed by Codex commodity committees, except for methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives; elaborates sampling plans and procedures, as may be required; considers specific sampling and analysis problems submitted to it by the Commission or any of its Committees; and defines procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.

The 37th Session of the Committee met in Budapest, Hungary, February 22–26, 2016. The relevant document is REP16/MAS. The following items will be considered by the Commission at its 39th Session in June 2016:

To be considered for adoption:

- Methods of Analysis and Sampling in Codex Standards; and
- Amendments to the Procedural Manual.

The Committee will continue working on:

- Guidance on the criteria approach for methods which use a "sum of components";
- Criteria for endorsement of biological methods to detect chemicals of concern;
- Procedures for determining uncertainty of measurement results (improvements and amendments to CAC/GL–54–2004);
- Review general guidelines on sampling (CAC/GL 50–2004) for potential revision;
- Practical examples on the selection of appropriate sampling plans; and
- Review and update of methods in Codex STAN 234–1999.

The following items have been discontinued:

- Development of procedures/guidelines for determining equivalency of Type I methods.

Responsible Agencies: HHS/FDA; USDA/Grain Inspection, Packers and Stockyards Administration.

U.S. Participation: Yes.

Codex Committee on Food Import and Export Inspection and Certification Systems

The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) is responsible for developing principles and guidelines for food import and export inspection and certification systems, with a view to harmonizing methods and procedures that protect the health of consumers, ensure fair trading practices, and facilitate international trade in foodstuffs; developing principles and guidelines for the application of measures by the competent authorities of exporting and importing countries to provide assurance, where necessary, that foodstuffs comply with requirements, especially statutory health requirements; developing guidelines for the utilization, as and when appropriate, of quality assurance systems to ensure that foodstuffs conform with requirements and promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries; developing guidelines and criteria with respect to format, declarations, and language of such official certificates as countries may require with a view towards international harmonization; making recommendations for information exchange in relation to food import/export control; consulting as necessary with other international groups working on matters related to food inspection and certification systems; and considering other matters assigned to it by the Commission in relation to food inspection and certification systems.

The 22nd Session of the Committee convened in Melbourne, Australia, February 6–12, 2016. The relevant document is REP16/FICS. There following items will be considered by the Commission at its 39th Session in June 2016:

To be considered for adoption at Step 5/8:

- Proposed draft Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food;
- Proposed draft Revision of the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19–1995); and
- Proposed draft Revision of the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25–1997).

To be considered for adoption at Step 5:

- Proposed draft Guidance for Monitoring the Performance of National Food Control Systems.

The Committee will continue working on:

- Discussion paper on the Use of Electronic Certificates by Competent Authorities and Migration to Paperless Certification;
- Discussion paper on Third Party Certification (with broad parameters);
- Discussion paper on Consideration of Emerging Issues and Future Directions for the Work of the Codex Committee on Food Import and Export Inspection and Certification Systems; and
- Discussion paper on Food Integrity/Food Authenticity As Emerging Issues.

Responsible Agencies: USDA/FSIS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Food Labelling

The Codex Committee on Food Labelling (CCFL) drafts provisions on labeling applicable to all foods; considers, amends, and endorses draft specific provisions on labeling prepared by the Codex Committees drafting standards, codes of practice, guidelines; and studies specific labeling problems assigned by the Codex Alimentarius Commission. The Committee also studies problems associated with the advertisement of food with particular reference to claims and misleading descriptions.

The Committee convened for its 43rd Session in Ottawa, Ontario, Canada May 9–13, 2016.

There following items will be considered by the Commission at its 39th Session in June 2016:

To be considered for adoption at Step 5:

- Revision of the General Standard for the Labelling of Prepackaged Foods: Date marking.

The Committee proposed that the Codex Alimentarius Commission identify a more appropriate forum for the revision of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Organic Aquaculture

The Committee agreed to propose new work on:

- Guidance for the labelling of Non-retail containers

The Committee will continue to work on:

- Front of Pack Labelling;
- Consideration of issues surrounding consumer preference claims; and
- Discussion paper on future work for the Committee.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Hygiene

The Codex Committee on Food Hygiene (CCFH):

- Develops basic provisions on food hygiene applicable to all food or to specific food types;
- Considers and amends or endorses provisions on food hygiene contained in Codex commodity standards and codes of practice developed by other Codex commodity committees;
- Considers specific food hygiene problems assigned to it by the Commission;
- Suggests and prioritizes areas where there is a need for microbiological risk assessment at the international level and develops questions to be addressed by the risk assessors; and
- Considers microbiological risk management matters in relation to food hygiene and in relation to FAO/WHO risk assessments.

The Committee convened for its 47th Session in Boston, Massachusetts, November 9–13, 2015. The relevant document is REP 16/FH. The following items will be considered by the Commission at its 39th Session in June 2016:

To be considered for adoption at Step 5/8:

- Guidelines for the Control of Non-Typhoidal *Salmonella* spp. in Beef and Pork Meat;
- Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites; and
- Proposed draft Annex I "Examples of Microbiological Criteria for Low-Moisture Foods when Deemed Appropriate in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21–1997)" and Annex II "Guidance for the Establishment of Environmental Monitoring Programs for *Salmonella* app. And other Enterobacteriaceae in Low-Moisture Food Processing Areas" to the Code of Hygienic Practice for Low-Moisture Foods (CAC/RCP 75–2015).

To be considered for adoption at step 8:

- Draft Annex III "Spices and Dried Aromatic Herbs" to the Code of Hygienic Practice for Low-Moisture Foods (CAC/RCP 75–2015)

To be considered for revocation:

- Code of Hygienic Practice for Spices and Dried Aromatic Herbs (CAC/RCP 42–1995)

The Committee will continue working on:

- Compiling all guidance for the control of foodborne parasites into a single document, *e.g.*, merging the General Principles of Food Hygiene to the Control of Foodborne Parasites and the Guidelines for the control of *Trichinella* spp. in meat of Suidae (CAC/GL 86–2015) and the Guidelines for the Control of *Taenia saginata* in meat of domestic cattle (CAC/GL 85–2014).

The Committee agreed to the following items for new work:

- Revision of the General Principles of Food Hygiene (CAC/RCP 1–1969) and its HACCP Annex;
- Revision of the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53–2003); and
- New work proposals/Forward Work plan.

Responsible Agencies: HHS/FDA; USDA/FSIS/.

U.S. Participation: Yes.

Codex Committee on Fresh Fruits and Vegetables

The Codex Committee on Fresh Fruits and Vegetables (CCFFV) is responsible for elaborating worldwide standards and codes of practice, as may be appropriate for fresh fruits and vegetables; for consulting as necessary, with other international organizations in the standards development process to avoid duplication.

The 19th Session of the Committee met in Ixtapa Zihuatanejo, Guerrero, Mexico October 5–9, 2015. The relevant document is REP 16/FFV. The following items will be considered at the 39th Session of the Codex Alimentarius Commission in June 2016.

To be considered for adoption at Step 5/8:

- Proposed draft Standard for Aubergines.

To be considered for adoption at Step 5:

- Proposed draft Standard for Garlic; and
- Proposed draft Standard for Kiwifruit.

The Committee will continue discussing the following items:

- Proposed draft Standard for Ware Potatoes;
- Proposals for new work for Codex standards for fresh fruits and vegetables;
- Layout for Codex standards for fresh fruits and vegetables;
- Selected provisions in the Layout for Codex/FFV standards pending further consideration by CCFFV; and
- Preparation of a draft Glossary of Terms for Application in the Layout for Codex Standards for Fresh Fruits and Vegetables.

Responsible Agencies: USDA/Agricultural Marketing Service (AMS); HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Nutrition and Foods for Special Dietary Uses

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is responsible for studying nutrition issues referred to it by the Codex Alimentarius Commission. The Committee also drafts general provisions, as appropriate, on nutritional aspects of all foods and develops standards, guidelines, or related texts for foods for special dietary uses in cooperation with other committees where necessary; considers, amends if necessary, and endorses provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines, and related texts.

The Committee convened for its 37th Session in Bad Soden am Taunus, Germany, November 23–27, 2015. The reference document is REP 16/NFSDU. The following items will be considered by the Commission at its 39th Session in June 2016:

To be considered for adoption:

- Draft amendment to the Annex of the Guidelines on Nutrition Labelling (CAC/GL 2–1985) to add a definition for RASBs (*i.e.* Recognized Authoritative Scientific Body); and
- Draft amendment to Section 10, Methods of analysis in Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex STAN 72–1981).

To be considered for adoption at Step 5/8:

- Proposed draft *Additional or Revised Nutrient Reference Values for Labelling Purposes* in the *Guidelines on Nutrition Labelling* (CAC/GL2–1985).

The Committee will continue working on:

- Proposed draft NRV–R for Vitamin D and the dietary equivalents and conversion factor for Vitamin E);
- Review if the Standard for Follow-Up Formula (CODEX STAN 156–1987) (Section 2.1.1 and 2.2 and essential composition and optional ingredients) (6–12 months);
- Review of the Standard for Follow-Up Formula (CODEX STAN 156–1987);
- Proposed draft Definition for Biofortification;
- Proposed draft NRV–NCD for EPA and DHA long chain omega-3 fatty acids;
- Proposed guideline for Ready-to-Use Foods (RUF);
- Discussion paper on Claim for "Free" of Trans Fatty Acids; and
- Alignment of Food Additive provisions in standards developed by CCNFSDU.

Responsible Agencies: HHS/FDA; USDA/Agricultural Research Service (ARS).

U.S. Participation: Yes.

Codex Committee on Fish and Fishery Products

The Fish and Fishery Products Committee (CCFFP) is responsible for elaborating standards for fresh, frozen and otherwise processed fish, crustaceans, and mollusks. The Committee convened for its 34th Session in Alesund, Norway October 19–24, 2015. The relevant document is REP16/FFP.

The following items will be considered by the 39th Session of the Commission in July 2016:

To be considered for approval:

- Sampling plans in the Standard for Live Abalone and for Raw, Fresh Chilled or Frozen Abalone for Direct Consumption or for Further Processing (CODEX STAN 312–2013); Standard for Smoked Fish, Smoked Flavored Fish and Smoke-Dried Fish (CODEX STAN 311–2013); and Standard for Fresh and Quick Frozen Raw Scallop Products (CODEX STAN 315–2014);
- Amendments to Food Additive Provisions in Standards for Fish and Fishery Products;
- Amendments to Section 7.4—Estimation of fish content of the Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets—Breaded or in Batter (CODEX STAN 166–1989); and
- Amendment to Section 11—Processing of salted and dried salted fish of the Code of Practice for Fish and Fishery Products (CAC/RCP52–2003).

The following items have recommended for discontinuation:

- Appendices 1–11 to the Code of Practice for Fish and Fishery Products (CAC/RCP 52–2003); and
- Proposal for a standard for fresh chilled pirarucu fillet or whole fish.

The Committee will continue working on:

- New work guidance for histamine control in the Code of Practice for Fish and Fishery Products (CAC/RCP 52–2003) and sampling plans for histamine in standards for fish and fishery products.

Responsible Agencies: HHS/FDA; DOC/NOAA/National Marine Fisheries Service (NMFS).

U.S. Participation: Yes.

Codex Committee on Fats and Oils

The Codex Committee on Fats and Oils (CCFO) is responsible for elaborating worldwide standards for fats and oils of animal, vegetable, and marine origin, including margarine and olive oil. The 25th Session of the Committee will meet in Kuala Lumpur, Malaysia, February 2017. The Committee will consider:

- Proposed draft *Standard for Fish Oils;*
- Amendments to Appendix 2 "List of Acceptable Previous Cargoes" of the *Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk* (CAC/RCP 36–1987);
- Addition of Palm Oil with High Oleic Acid (OxG);
- Revision of Fatty Acid Composition and Other Quality Factors of Peanut Oil;
- Revision of Limits of Oleic and Linoleic Acids in Sunflower Seed Oils; and
- Inclusion of provisions for Walnut Oil, Almond Oil, Hazelnut Oil, Pistachio Oil, Flaxseed Oil, and Avocado Oil.

Responsible Agencies: HHS/FDA; USDA/Agricultural Research Service (ARS).

U.S. Participation: Yes.

Codex Committee on Processed Fruits and Vegetables

The Codex Committee on Processed Fruits and Vegetables (CCPFV) is responsible for elaborating worldwide standards and related texts for all types of processed fruits and vegetables including, but not limited to canned, dried, and frozen products, as well as fruit and vegetable juices and nectars.

The Committee will convene its 28th Session in Washington, DC, September 12–16, 2016.

The committee will continue to discuss the following items:

- Proposed draft Annex on Canned Pineapples; and
- Proposed draft Annexes on Quick Frozen Vegetables. (Including methods of analysis for quick frozen vegetables)
- Amendments to food additive provisions in the standards for canned chestnuts and canned chestnut puree, canned bamboo shoots, canned mushrooms (certain canned vegetables), and pickles fruits and vegetables;
- Amendments to food additive and packing media provisions in Standard for Pickled Fruits and Vegetables;
- Status of work on the review/revision of Codex standards for processed fruits and vegetables; and
- Discussion paper on standardization of dry and dried produce.

Responsible Agencies: USDA/Agricultural Marketing Service; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Sugars

The Codex Committee on Sugars (CCS) elaborates worldwide standards for all types of sugars and sugar products.

The Committee has been reactivated electronically to work on a standard for Non-Centrifugated Dehydrated Sugar Cane Juice.

The following item will be considered by the Commission at its 39th Session in July 2016.

To be considered for adoption:

- Draft Standard for Non-Centrifugated Dehydrated Sugar Cane Juice at Step 6.

The Committee will continue working on:

- No additional work is ongoing in this Committee. It will again be adjourned *sine die* once the work on the Standard for Non-Centrifugated Dehydrated Sugar Cane Juice is adopted.

Responsible Agencies: HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Cereals Pulses & Legumes

The Codex Committee on Cereals Pulses & Legumes (CCCPL) elaborates worldwide standards and/or codes of practice as appropriate for cereals, pulses and legumes and their products.

The Committee has been reactivated electronically to draft an international quality standard for Quinoa.

- No additional work is ongoing in this Committee. It will again be adjourned *sine die* once the work on the international quality standard for Quinoa is adopted.

Responsible Agencies: HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Milk and Milk Products (CCMMP) elaborates worldwide standards, codes and related text for milk and milk products. The Committee has been reactivated to work by correspondence on a general standard for processed cheese, but has not reached consensus on that standard.

The Commission at its 39th Session in June 2016 will consider next steps for the Committee to take on this draft standard.

Responsible Agencies: USDA/AMS.

U.S. Participation: Yes.

Certain Codex Commodity Committees

Several Codex Alimentarius Commodity Committees have adjourned *sine die.* The following Committees fall into this category:

- Cocoa Products and Chocolate—adjourned 2001

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

- Meat Hygiene—adjourned 2003

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

- Natural Mineral Waters—adjourned 2008

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

- Vegetable Proteins—adjourned 1989

Responsible Agency: USDA/ARS.

U.S. Participation: Yes.

FAO/WHO Regional Coordinating Committees

The FAO/WHO Regional Coordinating Committees define the problems and needs of the regions concerning food standards and food control; promote within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulate the strengthening of food control infrastructures; recommend to the Commission the development of worldwide standards for products of interest to the region, including products considered by the Committees to have an international market potential in the future; develop regional standards for food products moving exclusively or almost exclusively in intra-regional trade; draw the attention of the Commission to any aspects of the Commission's work of particular significance to the region; promote coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within each region; exercise a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and promote the use of Codex standards and related texts by members.

There are six regional coordinating committees:

Coordinating Committee for Africa
Coordinating Committee for Asia
Coordinating Committee for Europe
Coordinating Committee for Latin America and the Caribbean
Coordinating Committee for the Near East
Coordinating Committee for North America and the South West Pacific

Coordinating Committee for Africa

The Committee (CCAfrica) will convene its 22nd Session January 16–20, 2017.

The Committee will discuss the following items:

- Proposed draft regional *Standard for dried meat, if approved as new work by the Commission at its June 2016 session;*
- Proposed draft *Regional Standard for fermented cooked cassava based products;*
- Proposed draft *Regional Standard for Shea Butter; and*
- Proposed draft *Regional Standard for Gnetum Spp. Leaves.*

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for Asia

The Committee (CCAsia) will convene its 20th Session in New Delhi, India, September 26–30, 2016.

The committee will discuss the following items:

- Key Note Address on Role of Codex in Strengthening National Food Control Systems in the Asian Region—A way forward;
- Food Safety and Quality Situation in the Countries of the Region;
- Prioritization of the Needs of the Region and Possible Approaches to Address Them;
- Use of Codex Standards in the Region: Relevance of Existing Regional Standards and Need for New Standards;
- Matters Arising from the Codex Alimentarius Commission and Other Codex Committees;
- Codex Work Relevant to the Region;
- Monitoring of the Implementation of the Codex Strategic Plan;
- Proposed draft Regional Standard for Laver Products;
- Proposed draft Regional Code of Hygienic Practice for Street-Vended Foods;
- Discussion paper on the Development of a Regional Standard for Makgeolli;
- Discussion paper on the Development of a Regional Standard for Natto; and
- Nomination of the Coordinator.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for Europe

The Committee (CCEurope) will convene its 30th Session in Astana Kazakhstan, October 3–7, 2016.

The Committee will discuss the following items:

- Regional Strategic Plan for CCEURO

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for Latin America and the Caribbean

The Coordinating Committee for Latin America and the Caribbean (CCLAC) will convene its 20th Session in Chile, November 21–25, 2016.

The Committee will discuss the following items:

- Proposed draft *Regional Standard for Yacon*

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for the Near East

The Committee (CCNEA) will convene its 9th Session in Iran, February 20–24, 2017.

The Committee will discuss the following items:

- Regional *Standard for Doogh;*
- Proposed draft *Regional Standard for Labneh;*
- Proposed draft *Regional Standard for Zaatar;*
- Discussion paper on a *Standard for Camel Milk;* and
- Draft Strategic Plan for CCNEA 2015–2020.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: No.

Coordinating Committee for North America and the South West Pacific (CCNASWP)

The Committee (CCNASWP) will convene its 14th Session in Port Vila Vanuatu, September 19–22, 2016.

The Committee will discuss the following items:

- Keynote address on the Multi-Sectorial Aspects of Codex and Opportunities for Strengthening Codex as a means to contribute to development of the economic, trade, agriculture, health, and nutrition sectors;
- Food safety and quality situation in the countries of the region;
- Prioritization of the needs of the region and possible approaches to address them;
- Use of Codex standards in the region: relevance of existing regional standards and need for new standards;

- Matters arising from the Codex Alimentarius Commission other Codex Committees;
- Codex work relevant to the region;
- Monitoring of the implementation of the Codex Strategic Plan (Strategic Plan for CCNASWP 2014–2019, Status of implementation);
- Proposed draft Regional Standard for Fermented Noni Juice;
- Discussion paper on the development of a Regional Standard for kava product that can be used as a beverage when mixed with water; and
- Nomination of the Coordinator.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes.

Contact

U.S. Codex Office, United States Department of Agriculture, Room 4861, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250–3700, Phone: (202) 205–7760, Fax: (202) 720–3157, Email: *uscodex@fsis.usda.gov.*

Attachment 2

U.S. Codex Alimentarius Officials

Codex Chairpersons From The United States

Codex Committee on Food Hygiene

Emilio Esteban, DVM, MBA, MPVM, Ph.D., Executive Associate for Laboratory Services, Office of Public Health Science, Food Safety and Inspection Service,U.S. Department of Agriculture, 950 College Station Road, Athens, GA 30605, Phone: (706) 546–3429, Fax: (706) 546–3428, Email: *emilio.esteban@fsis.usda.gov.*

Codex Committee on Processed Fruits and Vegetables

Richard Boyd, Chief, Contract Services Branch, Specialty Crops Program, Fruit and Vegetable Program, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Mail Stop 0247, Room 0726—South Building, Washington, DC 20250, Phone: (202) 690–1201, Fax: (202) 690–1527, Email: *richard.boyd@ams.usda.gov.*

Codex Committee on Residues of Veterinary Drugs in Foods

Kevin Greenlees, Ph.D., DABT, Senior Advisor for Science & Policy, Office of New Animal Drug Evaluation, HFV–100, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, Phone: +1 (240) 402–0638, Fax: +1 (240) 276–9538, *kevin.greenlees@fda.hhs.gov.*

U.S. Delegates and Alternate Delegates

General Subject Committees

Commodity Committees (Active and Adjourned)

ad hoc Task Forces

Regional Coordinating Committees

Worldwide General Codex Subject Committees

Contaminants in Foods (Host Government—The Netherlands)

U.S. Delegate

Dr. Lauren Posnick Robin, Branch Chief, Plant Products Branch, Division of Plant Products and Beverages, Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: +1 (240) 402–1369, *Lauren.Robin@fda.hhs.gov.*

Alternate Delegate

Terry Dutko, Laboratory Director, Food Safety and Inspection Service, OPHS, 4300 Goodfellow Building, 105D Federal, St. Louis, MO 63120–0005, Phone: +1 (314) 263–2680 Ext. 344, *Terry.Dutko@fsis.usda.gov.*

Food Additives (Host Government—China)

U.S. Delegate

Susan E. Carberry, Ph.D., Supervisory Chemist, Division of Petition Review, Office of Food Additive Safety (HFS–265), Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: +1 (240) 402–1269, Fax: +1 (301) 436–2972, *Susan.Carberry@fda.hhs.gov.*

Alternate Delegate

Paul S. Honigfort, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications (HFS–275), Office of Food Additive Safety, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: +1 (240) 402–1206, Fax: +1 (301) 436–2965, *Paul.Honigfort@fda.hhs.gov.*

Food Hygiene (Host Government—United States)

U.S. Delegate

Jenny Scott, Senior Advisor, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, HFS–300, Room 3B–014, College Park, MD 20740–3835, Phone: +1 (240) 402–2166, Fax: +1 (301) 436–2632, *Jenny.Scott@fda.hhs.gov.*

Alternate Delegates

Andrew Chi Yuen Yeung, Ph.D., Consumer Safety Officer, CFSAN, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, HFS–316, College Park, MD 20740, United States of America, Phone: +1 (240) 402–1541, Fax: +1 (301) 436–2632, *Andrew.Yeung@fda.hhs.gov.*

Dan Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, Jamie Whitten Building, Room 349–E, 1400 Independence Avenue SW., Washington, DC 20520, Phone: +1 (202) 720–8803, Fax: +1 (202) 720–3157, *Daniel.Engeljohn@fsis.usda.gov.*

Food Import and Export Certification and Inspection Systems (Host Government—Australia)

U.S. Delegate

Mary Stanley, Director, Office of International Coordination, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 2925, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250, Phone: +1 (202) 720–0287, Fax: +1 (202) 720–4929, *Mary.Stanley@fsis.usda.gov.*

Alternate Delegate

Vacant

Food Labelling (Host Government—Canada)

U.S. Delegate

Felicia B. Billingslea, Director, Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway (HFS–820), College Park, MD 20740, Phone: +1 (240) 402–2371, Fax: +1 (301) 436–2636, *Felicia.Billingslea@fda.hhs.gov.*

Alternate Delegate

Jeffrey Canavan, Deputy Director, Labeling and Program Delivery Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Mail Stop 5273, Patriots Plaza 3, 8th Floor–161A, Washington, DC 20250, Phone: +1 (301) 504–0860, Fax: +1 (202) 245–4792, *Jeff.Canavan@fsis.usda.gov.*

General Principles (Host Government—France)

Delegate Note: A member of the Steering Committee heads the delegation to meetings of the General Principles Committee.

Methods of Analysis and Sampling (Host Government—Hungary)

U.S. Delegate

Gregory Noonan, Director, Division of Bioanalytical Chemistry, Division of Analytical Chemistry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: +1 (240) 402–2250, Fax: +1 (301) 436–2332, *Gregory.Noonan@fda.hhs.gov.*

Alternate Delegate

Timothy Norden, Ph.D., Chief Scientist, Grain Inspection, Packers and Stockyards Administration (GIPSA) Technology & Science Division, U.S. Department of Agriculture, 10383 N. Ambassador Dr., Kansas City, MO 64153, USA, Phone: +1 (816) 891–0470, Fax: +1 (816) 891–8070, *Timothy.D.Norden@gipsa.usda.gov.*

Nutrition and Foods for Special Dietary Uses

(Host Government—Germany)

U.S. Delegate

Vacant.

Alternate Delegate

Pamela R. Pehrsson, Ph.D., Research Leader, USDA, Agricultural Research Service, Nutrient Data Laboratory, Room 105, Building 005, BARC-West, 10300 Baltimore Avenue, Beltsville, MD 20705, 301.504.0630 (voice), 301.504.0632, (fax), *Pamela.Pehrsson@ars.usda.gov.*

Pesticide Residues

(Host Government—China)

U.S. Delegate

David Miller, Chief, Chemistry & Exposure Branch and Acting Chief, Toxicology & Epidemiology Branch, Health Effects Division, William Jefferson Clinton Building, 1200 Pennsylvania Avenue NW., Washington, DC 20460, Phone: +1 (703) 305–5352, Fax: +1 (703) 305–5147, *Miller.Davidj@epa.gov.*

Alternate Delegate

Dr. Pat Basu, Senior Leader, Chemistry, Toxicology & Related Sciences, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 3805, Washington, DC 20250–3766, Phone: +1 (202) 690–6558, Fax: +1 (202) 690–2364, *Pat.Basu@fsis.usda.gov.*

Residues of Veterinary Drugs in Foods

(Host Government—United States)

U.S. Delegate

Brandi Robinson, MPH, CPH, ONADE International Coordinator, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, HFV–100, Rockville, MD 20855, Phone: +1 (240) 402–0645, *Brandi.Robinson@fda.hhs.gov.*

Alternate Delegate

Dr. Charles Pixley, DVM, Ph.D., Director, Laboratory Quality Assurance Staff, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, 950 College Station Road, Athens, GA 30605, Phone: +1 (706) 546–3559, Fax: +1 (706) 546–3453, *Charles.Pixley@fsis.usda.gov.*

Worldwide Commodity Codex Committees (Active)

Fats and Oils

(Host Government—Malaysia)

U.S. Delegate

Dr. Paul South, Director, Division of Plant Products and Beverages, Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD, USA 20740–3835, Phone: +1 (240) 402–1640, Fax: +1 (301) 436–2632, *Paul.South@fda.hhs.gov.*

Alternate Delegate

Robert A. Moreau, Ph.D., Research Leader, Eastern Regional Research Center, Agricultural Research Service, U.S. Department of Agriculture, 600 East Mermaid Lane, Wyndmoor, PA 19038, Phone: +1 (215) 233–6428, Fax: +1 (215) 233–6406, *Robert.Moreau@ars.usda.gov.*

Cereals, Pulses & Legumes

(Host Government—United States)

U.S. Delegate

Vacant.

Alternate Delegate

Mr. Patrick McCluskey, Supervisory Agricultural Marketing Specialist, United States Department of Agriculture, Grain Inspection, Packers and Stockyards Administration, 10383 N. Ambassador Drive, Kansas City, MO 64153, Phone: +1 (816) 659–8403, *Patrick.J.Mccluskey@usda.gov.*

Fish and Fishery Products

(Host Government—Norway)

U.S. Delegate

Dr. William Jones, Deputy Director, Division of Seafood Safety, Office of Food Safety (HFS–325), U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: +1 (240) 402–1700, Fax: +1 (301) 436–2601, *William.Jones@fda.hhs.gov.*

Alternate Delegate

Steven Wilson, Deputy Director, Office of International Affairs and Seafood Inspection, National Marine Fisheries Service, NOAA, U.S. Department of Commerce, 1315 East-West Highway, Silver Spring, Maryland 20910, Phone: +1 (301) 427–8312, *Steven.Wilson@noaa.gov.*

Fresh Fruits and Vegetables

(Host Government—Mexico)

U.S. Delegate

Dorian LaFond, International Standards Coordinator, Fruit and Vegetables Program, Specialty Crop Inspection Division, Agricultural Marketing Service, U.S. Department of Agriculture, Mail Stop 0247, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250–0247, Phone: +1 (202) 690–4944, Fax: +1 (202) 690–1527, *Dorian.Lafond@usda.gov.*

Alternate Delegate

Samir K. Assar, Ph.D., Director, Produce Safety Staff, Office of Food Safety, Food and Drug Administration, Phone: +1 (240) 402–1636, *Samir.Assar@fda.hhs.gov.*

Milk and Milk Products

(Host Government—New Zealand)

U.S. Delegate

Christopher Thompson, Dairy Standardization Branch, Stop 0230, Room 2742, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250, Phone: +1 (202) 720–9382, Fax: +1 (202) 720–2643, *Christopher.D.Thompson@ams.usda.gov.*

[FR Doc. 2016–15632 Filed 6–29–16; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Forest Service

Revision of Land and Resource Management Plan for the Santa Fe National Forest; Counties of Los Alamos, Mora, Rio Arriba, Sandoval, San Miguel, Santa Fe, and Taos, New Mexico

AGENCY: Forest Service, USDA.

ACTION: Notice of Intent to revise the Santa Fe National Forest Land and Resource Management Plan and to prepare an associated Environmental Impact Statement (EIS).

SUMMARY: The Forest Service is revising the Land and Resource Management Plan (hereafter referred to as the forest plan) for the Santa Fe National Forest. This notice describes the documents (assessment report, summaries of public meetings, preliminary needs-to-change statements) currently available for review and how to obtain them; summarizes the needs to change to the existing forest plan; provides information concerning public participation and engagement, including the process for submitting comments; provides an estimated schedule for the planning process, including the time available for comments, and includes the names and addresses of agency contacts who can provide additional information.

DATES: Comments concerning the Needs for Change and Proposed Action provided in this notice will be most useful in the development of the revised forest plan and draft EIS if received by August 5, 2016. The agency expects to release a draft revised forest plan and draft EIS by summer, 2017 and a final revised forest plan and final EIS by fall, 2018.

ADDRESSES: Written correspondence can be sent to: Santa Fe National Forest, Attn: Forest Plan, 11 Forest Lane, Santa Fe, NM 87508, or emailed to *santafeforestplan@fs.fed.us*.

FOR FURTHER INFORMATION CONTACT: Jennifer Cramer, Forest Planner, Santa Fe National Forest, 11 Forest Lane, Santa Fe, New Mexico 87508. More information on our forest plan revision process can be found on our Web site at *www.fs.usda.gov/goto/santafeforestplan*. If you have questions or would like to sign-up for our mailing list, you can email *santafeforestplan@fs.fed.us* or call our Forest Plan Revision number: 505–438–5442. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The National Forest Management Act (NFMA) of 1976 requires that every National Forest System (NFS) unit develop a forest plan. On April 9, 2012, the Forest Service finalized its land management planning rule (2012 Planning Rule, 36 CFR 219), which describes requirements for the planning process and the content of the forest plans. Forest plans describe the strategic direction for management of forest resources for ten to fifteen years, and are adaptive and amendable as conditions change over time. Under the 2012 Planning Rule, the assessment of ecological, social, and economic conditions and trends is the first stage of the planning process (36 CFR 219.6). The second stage, formal plan revision, involves the development of our forest plan in conjunction with the preparation of an Environmental Impact Statement under the NEPA. The third stage of the process is monitoring and feedback, which is ongoing over the life of the revised forest plans.

The Santa Fe National Forest has completed its assessment pursuant to 2012 Forest Planning Rule. The assessment was developed with public participation and includes an evaluation of existing information about relevant ecological, economic, cultural and social conditions, trends, and sustainability and their relationship to forest plans within the context of the broader landscape. The intent of the Santa Fe National Forest is that this information builds a common understanding prior to entering formal plan revision. With this notice, the Santa Fe National Forest is initiating formal plan revision and invites other governments, non-governmental parties, and the public to contribute. The intent of public engagement is to inform development of the plan revision. We encourage contributors to share material that may be relevant to the planning process, including desired conditions for the Santa Fe National Forest. As we develop public engagement opportunities to assist with the plan revision phase, public announcements will be made and information will be posted on the Forest's Web site: *www.fs.usda.gov/goto/santafeforestplan*. If you would like to contribute to the process or for more information, please call 505–438–5442, email *santafeforestplan@fs.fed.us*, or contact Jennifer Cramer, Forest Planner, Santa Fe National Forest, 505–438–5449.

Name and Address of the Responsible Official

The Responsible Official for the revision of the forest plan for the Santa Fe National Forest is Maria T. Garcia, Forest Supervisor, Santa Fe National Forest, 11 Forest Lane, Santa Fe, New Mexico 87508.

Nature of the Decision To Be Made

The Santa Fe National Forest is proposing to revise the existing forest plan and is preparing an EIS to inform the Forest Supervisor so she can decide which alternative best maintains and restores National Forest System terrestrial and aquatic resources while providing ecosystem services and multiple uses, as required by the National Forest Management Act and the Multiple Use Sustained Yield Act.

The revised forest plan will describe the strategic intent of managing the Santa Fe National Forest for the next 10 to 15 years and will address the identified needs for change to the existing forest plan. The revised forest plan will provide management direction in the form of desired conditions, objectives, standards, guidelines, and suitability of lands. It will identify delineation of new management areas and potentially geographic areas across the Forest; identify the timber sale program quantity; make recommendations to Congress for Wilderness designation; and list rivers and streams eligible for inclusion in the National Wild and Scenic Rivers System. The revised forest plan will also provide a description of the plan area's distinctive roles and contributions within the broader landscape, identify watersheds that are a priority for maintenance or restoration, include a monitoring program, and contain information reflecting expected possible actions over the life of the forest plan.

The revised forest plan will represent decisions that are strategic in nature, but will not make site-specific project decisions and will not dictate day-to-day administrative activities needed to carry on the Forest Service's internal operations. The authorization of project level activities will be based on the guidance/direction contained in the revised forest plan, but will occur through subsequent project specific NEPA analysis and decision-making.

The revised forest plan will provide broad, strategic guidance that is consistent with other laws and regulations. Though strategic guidance will be provided, no decisions will be made regarding the management of individual roads or trails, such as those might be associated with a Travel

Management plan under 36 CFR part 212. Some issues (*e.g.*, hunting regulations), although important, are beyond the authority or control of the National Forest System and will not be considered. No decision regarding oil and gas leasing availability will be made, though plan components may be brought forward or developed that will help guide the development of oil & gas leasing decisions that might be necessary in the future.

Purpose and Need (Needs for Change) and Proposed Action

According to the National Forest Management Act, forest plans are to be revised every 10 to 15 years. The proposed action is to revise the forest plan to address the identified needs for change to the existing forest plan. Alternatives to the proposed action will be developed to address significant issues identified through scoping.

The purpose and need for revising the current forest plan are to: (1) Update the forest plan which was approved in 1987 and is over 29 years old, (2) reflect changes in economic, social, and ecological conditions, new policies and priorities, and new information based on monitoring and scientific research, and (3) address the preliminary identified needs for change to the existing forest plan, which are summarized below. Extensive public and interdisciplinary team involvement, along with science-based evaluations, have helped to identify these preliminary needs for change to the existing forest plan.

What follows is a summary of the preliminary identified needs for change to the existing forest plan. A more fully developed description of the preliminary needs for change, which has been organized into several resource and management topic sections, is available for review on the plan revision Web site at: *www.fs.usda.gov/goto/santafeforestplan.*

The Santa Fe National Forest has identified twelve focus areas, the first topics presented below, that have the greatest needs for new or different plan direction. Needs for change for additional resources follow and represent additional cases where changes are needed in plan direction. Overall, there is a need for plan direction that is strategic and identifies desired conditions with objectives for how resources should be managed; eliminates redundancies with existing laws, regulations and policy; removes requirements to prepare additional resource plans; and that incorporates the best available scientific information (BASI) into all plan components.

Monitoring. Monitoring is a critical element of adaptive management, and the plan monitoring program needs to be focused to be effective. Monitoring questions that are relevant to plan components including desired conditions, standards, guidelines, suitability and other strategic goals of the revised forest plan are needed. In addition, monitoring at appropriate scales is needed, including monitoring beyond the Santa Fe National Forest boundary to compare resources on the forest with their status on a larger context scale or even between neighboring forests.

Relationships & Partners. Relationships and effective partnerships are key to the successful implementation of the forest plan that will protect the land and serve the people. Management approaches are needed to both streamline the processes that leverage partners and volunteers and build stronger relationships with the public, including but not limited to state and federal agencies, cities and counties, tribal governments, recreational and forest user groups, environmental groups, land grant communities and other traditional communities, local communities, youth, and vendors. Management approaches are also needed that will emphasize public education regarding the Santa Fe National Forest's diverse ecological, social, and economic resources, the multiple-use philosophy, public laws and regulations, and management strategies.

Frequent Fire (Low Severity) Systems. Fire exclusion and past management activities have limited frequent, low-severity wildfires on the landscape. Wildfire atypical of historic fire regimes has resulted from higher densities of trees, increased fuel loadings, and altered species composition from mature, fire-tolerant species toward shade-tolerant, less fire-resistant species. There is a need for plan direction that recognizes the natural processes of fire and its use as a management tool for vegetation types on the Santa Fe National Forest and that supports integrated resource objectives.

Grass Cover. Grassland, woodland and shrubland have significantly less grass cover and productivity as a result of legacy (historical) grazing from livestock, wildlife grazing, roads, and the exclusion of wildfire. This lack of cover contributes to reduced water infiltration, accelerated erosion and declining soil productivity, especially during periods of drought and contributes to a cycle that continues to reduce vegetative cover. In addition, native grasses on much of the landscape have been replaced with non-native and/or invasive species and are not as effective in the prevention of erosion or as productive for forage. There is a need for desired conditions and standards and guidelines that allow for the restoration, conservation, and maintenance of grass productivity and diversity, emphasizing native grasses. Desired conditions that limit and reverse woody species encroachment into grasslands and infill of shrublands, woodlands, and forested systems are also needed.

Riparian Ecosystems. Riparian systems have been degraded and are at risk across the forest. A variety of land uses (*e.g.*, roads, grazing, recreation), increased water demand (water withdrawal) and climatic changes (*e.g.*, long-term drought) have deteriorated these systems. There is a need for desired conditions to restore or maintain characteristic composition and cover of riparian vegetation. There is a need for standards and guidelines that minimize the ecological impacts of multiple uses in riparian areas, and a recognition of their reliance on upland ecological health.

Restoration of Ecosystem Resiliency. Resiliency is the ability of an ecosystem to regain structure, composition, and function following disturbance on a time span that is consistent with the dynamics of the ecosystem. There is a need for plan direction that recognizes the interdependence of resources, provides for management areas that reflect natural features and/or ecological boundaries, incorporates adaptive management components to better respond to changing environmental conditions, and support an all-lands approach of working with neighboring land managers to implement projects that improve landscape connectivity across mixed ownerships where natural systems span multiple administrative boundaries. In addition, desired conditions are needed that promote natural disturbance processes that sustain forest carbon sequestration and emphasize silvicultural practices of uneven-aged management, and standards and guidelines that limit non-native species while encouraging native species.

Water. Both natural and human-caused disturbances have degraded water quality and quantity. As population around the Santa Fe National Forest increases, the lack of surface water will place a greater demand on groundwater resources which may further deplete surface flows both on and off the forest. There is a need for plan direction to protect stream channels, hydrological function and condition of water-dependent systems by maintaining and restoring upland and riparian vegetative cover and reducing erosion and sedimentation from disturbed sites (*e.g.,* reclaiming roads) where feasible. There is also a need for plan direction which provides for sustainable groundwater-dependent ecosystems (*e.g.,* seeps and springs, fens, and wetlands) and for the long-term protection of groundwater quality and quantity on the Santa Fe National Forest. There is a need for plan direction that considers consumptive water uses and water rights because water is over allocated and will continue to be in high demand.

Soils. Soil condition, and soil erosion hazard are directly linked to site productivity and soil resilience, and current soil loss rates exceed natural soil loss rates across the Santa Fe National Forest. The majority of the Santa Fe National Forest has a high probability for accelerated erosion due to natural disturbances or management disturbances that expose the soil surface without incorporating erosion control measures. There is a need for plan direction that promotes the maintenance and restoration of soil condition and function (*e.g.,* hydrology, stability, and nutrient cycling) by limiting the amount of exposed soil and by restoring and maintaining sufficient vegetative cover.

Range. Vegetation analyses show that the grassland types commonly used for livestock grazing are losing productivity due to declines in herbaceous ground cover, invasive species and drought. Other key influences include fractured ownership of private lands, legal uncertainties about land titles, and endangered species listings by the U.S. Fish and Wildlife Service, including the New Mexico Meadow Jumping Mouse. There is a need for plan direction that provides opportunities to use adaptive management for the range program that incorporates ecosystem-based desired conditions, with particular emphasis on strategies to address drought and other extreme weather-related events.

Recreation. The ability of the Santa Fe National Forest to provide a meaningful recreation program is at risk, reflecting increasing and changing demands in a resource-constrained management environment. There is a need for plan direction on sustainable recreation management to provide high quality recreational experiences that are consistent with the Santa Fe National Forest's social, environmental, and economical resource capacity while balancing changing trends in services and intended use of recreation infrastructure and facilities. Plan direction is also needed to help manage recreation activity impacts to areas sensitive to resource degradation or at risk due to high visitation and to reduce user conflicts.

Infrastructure. The Santa Fe National Forest's ability to maintain its current infrastructure is severely threatened. Of the approximately 6,900 miles of roads on the landscape, 2,200 miles of roads are open to the public for motorized use. The remaining 4,700 miles of roads may be administrative use roads or non-system roads, and most contribute to erosion and sedimentation, reflecting a critical and growing gap in resources for maintenance. There is also infrastructure related to rural and agronomic uses, such as timber harvesting, grazing, and rangeland management. Much of the range infrastructure across the forest is non-functional and/or in need of maintenance or decommissioning. Non-functional water developments and downed fencing result in cattle seeking water in sensitive riparian areas. Unmaintained and vandalized range improvements can also be hazardous for wildlife. There is a need for plan direction to ensure sustainable infrastructure (*e.g.,* roads, recreation and administrative facilities, range improvements, maintenance, etc.) and standards and guidelines that address negative impacts of existing roads.

Land Status and Ownership. The Lands Program on the Santa Fe National Forest has increasing demands for services such as managing access to private inholdings, managing encroachments from private land onto Forest Service land, title claims, evolving requests for communication sites, the ever-growing Wildland Urban Interface area, completing property boundary surveys, and fragmentation. There is a need for plan direction regarding access to private lands, including during evaluation of placement of infrastructure, to minimize natural resource damage while ensuring rights of access to private lands are respected. Due to growing demand, plan direction regarding sites for communications infrastructure is needed. Plan direction is also needed to protect existing public access rights and provide for new recreational access opportunities to National Forest lands. Management approaches that support coordination between local governments and the Forest Service regarding permits, leases, and easements on National Forest lands are needed.

Wildlife, Fish, and Plants. There is a need for plan direction that supports restoration and maintenance of ecological conditions that contribute to the recovery and conservation of federally listed species (threatened and endangered), maintaining viable populations of the species of conservation concern, and maintaining common and abundant species. In addition, plan direction for terrestrial and aquatic habitat connectivity for species migration and movement is needed.

Air. There is a need for plan direction for air quality in terms of ambient air quality, visibility, and critical loads.

Socioeconomic Resources. There is a need for plan direction that recognizes the Santa Fe National Forest's role in contributing to traditional and cultural forest uses and local economies, including service-based sectors such as recreation and tourism, timber, and other multiple-use related activities and products.

Designated Areas. There is a need for plan direction to identify and evaluate potential additions to the National Wilderness Preservation System and eligibility for inclusion in the National Wild and Scenic Rivers System. In addition, plan direction for designated and recommended wilderness areas is needed to protect and enhance wilderness values and character.

Scenery. There is a need for plan direction to integrate scenery management into all resource management decisions with the intent of retaining and enhancing scenic resources while integrating with other resources (*e.g.,* restoration, habitat diversity, and timber management).

Cultural Resources. There is a need for plan direction to stabilize, preserve, interpret, and protect historic and sensitive properties, (*e.g.,* archaeological sites, historic structures, and traditional cultural properties). There is also a need for plan direction that recognizes the inherent value and preservation of Native American traditional cultural properties and sacred sites, as well as non-Native American traditional cultural properties, while maintaining the anonymity of such sites where appropriate.

Traditional and Cultural Ways of Life. There are deep and historic ties between nearby populations and the Santa Fe National Forest, and the revised plan needs to recognize and protect historic and contemporary cultural uses—both economic and non-economic—for tribes as well as traditional communities not considered under tribal relations (*e.g.* traditional Hispanic and Anglo communities).

Areas of Tribal Importance. There is a need for management approaches that include opportunities for integrating forest management with tribal needs through shared stewardship to address threats to adjacent tribal resources (*e.g.,* through the Tribal Forest Protection Act of 2004), to meet common objectives identified in tribal and pueblo land management plans, and to utilize an "all lands" approach to resources management.

Extractive multiple uses. There is a need for plan direction that provides for the use of a variety of forest products by commercial, noncommercial, tribal, and land grant users. There is a need for plan direction that allows for flexible size criteria regarding timber extraction to balance desired conditions and the ability to provide economically viable forest products. There is a need for plan direction regarding traditional and alternative energy sources that balances demand with natural resource impacts.

Public Involvement

A Notice of initiating the assessment phase of forest plan revision for the Santa Fe National Forest was published in the **Federal Register** on March 6, 2014 (79 FR 12686). Prior to the formal initiation of the assessment, the Santa Fe National Forest held 27 joint listening sessions with the Carson National Forest and two workshops to solicit comments, input, and desires from the public, governmental entities, tribes, land grants, and nongovernmental organization for public participation through the forest plan revision process. In April and May 2014, fourteen public meetings provided an introduction to forest plan revision and an opportunity for the public to provide input for the assessment by expressing how they use and value the forest, and what trends or changes they have observed. This information was directly incorporated into the assessment report for the Santa Fe National Forest "Input Received from Public Meetings". In April and May 2015, the Santa Fe and Carson National Forests jointly held three meetings with members of local land grants, to present and discuss the plan revision process. In October 2015, the forest held a symposium to present detailed findings from the assessment followed by ten public and two tribal work sessions on developing Need for Change statements. Additionally, the Santa Fe National Forest has been informing and engaging communities at a local level through presentation at meetings hosted by organizations, government groups and Tribes; informational booths at fairs and local community events; and presentations and field trips for local schools.

Any comments related to the Santa Fe National Forest's assessment report that are received following the publication of this Notice may be considered in the draft and final environmental impact statements.

Scoping Process

Written comments received in response to this notice will be analyzed to complete the identification of the needs for change to the existing forest plan, further develop the proposed action, and identify potential significant issues. Significant issues will, in turn, form the basis for developing alternatives to the proposed action. Comments on the preliminary needs for change and proposed action will be most valuable if received by August 17, 2016, and should clearly articulate the reviewer's opinions and concerns. Comments received in response to this notice, including the names and addresses of those who comment, will be part of the public record. Comments submitted anonymously will be accepted and considered in the NEPA process; however, anonymous comments will not provide the Agency with the ability to provide the respondent with subsequent environmental documents. See the below objection process material, particularly the requirements for filing an objection, for how anonymous comments are handled during the objection process. Refer to the Forest's Web site (*www.fs.usda.gov/goto/santafeforestplan*) for information on when public meetings will be scheduled for refining the proposed action and identifying possible alternatives to the proposed action.

Applicable Planning Rule

Preparation of the revised forest plan for the Santa Fe National Forest began with the publication of a Notice of Assessment Initiation in the **Federal Register** on March 6, 2014 (79 FR 12686) and was initiated under the planning procedures contained in the 2012 Forest Service planning rule (36 CFR 219 (2012)).

Permits or Licenses Required To Implement the Proposed Action

No permits or licenses are needed for the development or revision of a forest plan.

Decisions Will Be Subject To Objection

The decision to approve the revised forest plan for the Santa Fe National Forest will be subject to the objection process identified in 36 CFR part 219 Subpart B (219.50 to 219.62). According to 36 CFR 219.53(a), those who may file an objection are individuals and entities who have submitted substantive formal comments related to forest plan revision during the opportunities provided for public comment during the planning process.

Documents Available for Review

The Needs for Change documentation, the Assessment Report, summaries of the public meetings and public meeting materials, and public comments and responses are posted on the Forest's Web site at: *www.fs.usda.gov/goto/santafeforestplan.* As necessary or appropriate, the material available on this site will be further adjusted as part of the planning process using the provisions of the 2012 planning rule.

Authority: 16 U.S.C. 1600–1614; 36 CFR part 219 [77 FR 21260–21273].

Dated: June 23, 2016.

Joseph S. Norrell,

Deputy Forest Supervisor.

[FR Doc. 2016–15525 Filed 6–29–16; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Appeal of Decisions Relating to Occupancy or Use of National Forest System Lands and Resources

AGENCY: Forest Service, USDA.

ACTION: Notice; requests for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments on the renewal of a currently approved information collection.

DATES: Comments must be received in writing by August 29, 2016 to be considered.

ADDRESSES: Comments concerning this notice should be addressed to USDA Forest Service, Deb Beighley, Assistant Director, Appeals and Litigation, Ecosystem Management Coordination staff, 202–205–1277 or by email to *dbeighley@fs.fed.us.*

The public may inspect comments received at the Office of Ecosystem Management Coordination, Appeals & Litigation USDA Forest Service, 201 14th Street SW., Mail Stop 1104, Washington, DC 20024–1101, during normal business hours. Visitors are encouraged to call ahead at 202–791–8488 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Deb Beighley, Assistant Director, Appeals and Litigation, Ecosystem Management Coordination staff, 202–205–1277. Individuals who use telecommunication devices for the deaf may call the Federal Relay Service at 800 877–8339 twenty four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Appeal of Decisions Relating to Occupancy or Use of National Forest System Lands and Resources.

OMB Number: 0596–0231.

Expiration Date of Approval: August 31, 2016.

Type of Request: Renewal of a currently approved information collection, approval of an associated new information collection, Appeal of Decisions Relating to Occupancy or Use of National Forest System Lands and Resources.

Abstract: This appeal process modifies, renames, and relocates to a new part in the CFR the appeal process for decisions related to occupancy or use of NFS lands and resources. This updated regulation will simplify the appeal process, shorten the appeal period, and reduce the cost of appeal for certain types of Forest Service decisions affecting occupancy or use of NFS lands and resources. The information collected will be used by the Forest Service to determine if the decision that was appealed should be affirmed or reversed in whole or in part. These appeal procedures are limited to holders, operators, and solicited applicants as defined in the proposed rule, who therefore are the only individuals or entities subject to the information collection requirement.

The information collection required for the administrative appeal process in 36 CFR part 214 is approved and assigned OMB Control No. 0596–0231.

Estimate of Annual Burden: 8 hours per application.

Type of Respondents: People Appealing Decisions to Occupancy or Use of National Forest System Lands and Resources decisions.

Estimated Annual Number of Respondents: 70.

Estimated Annual Number of Responses per Respondent: One.

Estimated Total Annual Burden on Respondents: 560 hours.

Public Comment: Public comment is invited on (1) whether this information collection is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for OMB approval of the information collection.

Dated: June 23, 2016.

Leslie A.C. Weldon,

Deputy Chief, National Forest System.

[FR Doc. 2016–15407 Filed 6–29–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Deschutes Provincial Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Deschutes Provincial Advisory Committee (PAC) will meet in Bend, Oregon. The committee is authorized pursuant to the implementation of E–19 of the Record of Decision and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to provide advice and make recommendations to promote a better integration of forest management activities between Federal and non-Federal entities to ensure that such activities are complementary. PAC information can be found at the following Web site: *http://www.fs.usda.gov/detail/deschutes/workingtogether/advisorycommittees.*

DATES: The meeting will be held on July 29, 2016, from 9:00 a.m. to 4:00 p.m.

All PAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Deschutes National Forest Headquarters Office, Ponderosa Conference Room, 63095 Deschutes Market Road, Bend, Oregon. The Committee will also be traveling to sites on the Deschutes National Forest.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Deschutes National Forest Headquarters Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Beth Peer, PAC Coordinator, by phone at 541–383–4769 or via email at *bpeer@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear a presentation on climate change and water;
2. Review restoration thinning and fuels reduction operations on the Forest; and
3. Visit Ryan Ranch wetland restoration project area.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by July 15, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Beth Peer, Deschutes PAC Coordinator, 63095 Deschutes Market Road, Bend, Oregon 97701; by email to *bpeer@fs.fed.us,* or via facsimile to 541–383–4755.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation, For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: June 20, 2016.

John P. Allen,

Forest Supervisor, Deschutes National Forest.

[FR Doc. 2016–15524 Filed 6–29–16; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska State Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

DATES: Thursday, June 30, 2016. Time: 12:00 p.m.–1:00 p.m. (Alaska Time).

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska State Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Alaska Time) Thursday, June 30, 2016 for the finalizing panels and panelists for the Alaska State Advisory Committee's new project for FY 2016 identifying possible barriers in the election process that may disparately impact limited English proficient (LEP) Alaskan persons based upon the impact of recent settlements regarding voting access, as well as the recent pre-clearance changes to the Voting Rights Act of 1965.

This meeting is available to the public through the following toll-free call-in number: Toll-Free Phone Number: 888–395–3227; when prompted, please provide conference ID number: 2154626.

Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number.

Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments within thirty (30) days of the meeting. The comments must be received in the Western Regional Office of the Commission by Friday, July 29, 2016. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 2010, Los Angeles, CA 90012. Persons wishing to email their comments may do so by sending them to Angela French-Bell, Regional Director, Western Regional Office, at *abell@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=234.* Please click on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Western Regional Office at the above email or street address.

Agenda for June 30, 2016

I. Introductory Remarks
II. Discussion of Panels for Briefing Meeting
III. Discussion of Panelists for Briefing Meeting
IV. Discussion of Briefing Meeting
V. Public Comment
VI. Adjournment

This meeting is available to the public through the following toll-free call-in number: Toll-Free Phone Number: 888–395–3227; when prompted, please provide conference ID number: 2154626.

FOR FURTHER INFORMATION CONTACT: Angela French-Bell, DFO, at (213) 894–3437 or *abell@usccr.gov.*

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of a deadline to complete the project report. Given the exceptional urgency of the events, the agency and advisory committee deem it important for the advisory committee to meet on the date given.

Dated June 27, 2016.

David Mussatt,

Chief, Regional Programs Coordination Unit.

[FR Doc. 2016–15535 Filed 6–29–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Local Update of Census Addresses Operation

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, submit written comments on or before August 29, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the information collection instrument(s) and instructions to Robin A. Pennington, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233 (or via the Internet at *robin.a.pennington@census.gov*).

SUPPLEMENTARY INFORMATION

I. Abstract

The U.S. Census Bureau developed the Local Update of Census Addresses (LUCA) Operation prior to the 2000 Census to meet the requirements of the Census Address List Improvement Act of 1994, Public Law 103–430. The Census Bureau will use information collected through LUCA to help develop the housing unit and group quarters (*e.g.,* college dormitory, nursing home, correctional facility) address information that it will need to conduct the Decennial Census. LUCA is a voluntary operation for governmental units. Participating governments may review the Census Bureau's Title 13 U.S.C. confidential list of individual living quarters addresses and provide to the Census Bureau address additions, corrections, deletions, structure point coordinates, and road updates. Participating governments also may provide spatial and attribute updates for addresses and roads. Governments electing to participate in LUCA also provide contact information, certification of their agreement to maintain the confidentiality of the Census Bureau address information, responses regarding their physical and information technology security capability, product media preference information, shipment inventory information, and certification of their destruction or return of materials containing confidential data.

LUCA will be available to tribal, state, and local governments, the District of Columbia, and Puerto Rico (or their designated representatives) in areas for which the Census Bureau performs a pre-census Address Canvassing Operation. A majority of governments will have some area that will be included in the Address Canvassing Operation. LUCA is available to legally defined federally recognized Native American and Alaska Native areas (including the Alaska Native Regional Corporations), states, governmentally active counties and equivalent entities, incorporated places, and legally defined Minor Civil Divisions (MCDs) for which the Census Bureau reports data. LUCA will occur between January 2017 and June 2020. LUCA comprises five stages:

- Advance Notice
- Invitation
- Address Review
- Feedback
- Closeout

Advance Notice

The Census Bureau provides an advance notice package to all eligible tribal, state, and local governments. This package contains materials informing the eligible governments of the voluntary operation and provides instructions to update contact information and how to prepare to participate in the operation. This stage occurs between January 2017 and March 2017.

Invitation

All eligible tribal, state, and local governments receive an invitation package. This package provides information on how to register for the operation and instructions on how to designate a liaison, and allows governments to select the type of materials. Additionally, the invitation package provides information regarding the responsibility for safeguarding and protecting Title 13 materials. The Census Bureau will follow up and send reminder packages to governments that do not respond. This stage occurs between July 2017 and September 2017.

Address Review

Governments that elect to participate receive materials based on their selection from the invitation package. Governments have a maximum of 120 days from the date of receipt of materials to complete and submit their address and spatial updates to the Census Bureau. The Census Bureau will conduct follow up with letters, postcards, and phone calls to encourage timely submission of address and spatial updates. This stage occurs between February 2018 and May 2018.

Feedback

The Census Bureau will provide a feedback package to governments that participate in the operation. This package includes detailed information on the results of the address and spatial updates submitted during the operation. This stage occurs between August 2019 and October 2019.

Closeout

The Census Bureau provides a closeout letter to governments that participated in the operation with notification to destroy or return Title 13 materials. The Census Bureau will also conduct follow up with letters and phone calls to ensure that Title 13 materials are destroyed or returned. This stage occurs between October 2019 and June 2020.

II. Method of Collection

The information on LUCA contacts, certification of agreement to maintain the confidentiality of the Census Bureau address information, physical and information technology security capability, product media preference, shipment inventory, and certification of the destruction or return of materials containing confidential data is collected via the completion of electronic or printed forms.

Address Updates

The information collection on living quarters address additions, corrections, deletions, and address attribute updates, at the participating government's preference, can be submitted in the form of:

1. Digital data files output by the Geographic Update Partnership Software (GUPS), a desktop application supplied free-of-charge to LUCA participants to facilitate the review and update of Census Bureau address and map information;
2. Digital data files formatted to Census Bureau specifications; or
3. Handwritten annotations to printed-paper address listings and address locations on Census block maps (for governments with 6,000 or fewer addresses).

Feature Updates

The information collection on living quarters structure point coordinates, roads, and road attribute updates, at the participating government's preference, can be submitted in the form of:

1. Digital data shapefiles output by GUPS;
2. Digital updates to Census Bureau supplied shapefiles; or
3. Handwritten annotations on Census Bureau supplied paper maps.

III. Data

OMB Control Number: 0607–XXXX.

Form Numbers: D–2001–Contact Information Update Form, D–2001–SP–Contact Information Update Form (Spanish), D–2002–Registration Form, D–2002–SP–Registration Form (Spanish), D–2003–Product Preference Form, D–2003–SP–Product Preference Form (Spanish), D–2003–SG–GIS Preference/County Selection Form (State Governments), D–2004–Confidentiality and Security Guidelines, D–2004–SP–Confidentiality and Security Guidelines (Spanish), D–2005–Confidentiality Agreement Form, D–2005–SP–Confidentiality Agreement Form (Spanish), D–2006–Self–Assement Security Checklist, D–2006–SP–Self–Assessment Security Checklist (Spanish), D–2007–Address List, D–2007–SP–Address List (Spanish), D–2008–Address List Add Page, D–2008–SP–Address List Add Page (Spanish), D–2009–Address Count List, D–2009–SP–Address Count List (Spanish), D–2010–Map Sheet to Block Number Relationship List, D–2010–SP–Map Sheet to Block Number Relationship List (Spanish), D–2011–Inventory Return Form, D–2011–SP–Inventory Return Form (Spanish), D–2012–Destruction or Return Form, and D–2012–SP–Destruction or Return Form (Spanish).

Type of Review: Regular submission.

Affected Public: Tribal, state, and local governments.

Estimated Number of Respondents: 40,000.

Estimated Time per Response: 129.5 hours on average; will vary by population size of government.

Estimated Total Operation Hours: 5,180,000

Estimated Total Operation Cost to Public: $146,127,800.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Chapter 1, Subchapter 1, Section 16.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection;

they also will become a matter of public record.

Dated: June 27, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–15495 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Current Population Survey, Voting and Registration Supplement.

OMB Control Number: 0607–0466.

Form Number(s): There are no forms. We conduct all interviews on computers.

Type of Request: Regular Submission.

Number of Respondents: 52,000.

Average Hours per Response: 1.5 minutes.

Burden Hours: 1,300.

Needs and Uses: This survey has provided statistical information for tracking historical trends of voter and nonvoter characteristics in each Presidential or Congressional election since 1964. The data collected from the November supplement relates demographic characteristics (age, sex, race, education, occupation, and income) to voting and nonvoting behavior. The November CPS supplement is the only source of data that provides a comprehensive set of voter and nonvoter characteristics distinct from independent surveys, media polls, or other outside agencies. Federal, state, and local election officials use these data to formulate policies relating to the voting and registration process. College institutions, political party committees, research groups, and other private organizations also use the voting and registration data.

Affected Public: Individuals or households.

Frequency: Biennial.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 141 and 182; and Title 29, U.S.C., Sections 1–9.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Dated: June 27, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–15498 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–43–2016]

Foreign-Trade Zone 158—Tupelo, Mississippi; Notification of Proposed Production Activity; Bauhaus Furniture Group, LLC; H.M. Richards Company, Inc.; Lane Home Furniture; Morgan Fabrics Corporation (Upholstered Furniture)

The Greater Mississippi Foreign-Trade Zone, Inc., grantee of FTZ 158, submitted a notification of proposed production activity to the FTZ Board on behalf of Bauhaus Furniture Group, LLC (Bauhaus), H.M. Richards Company, Inc. (HMRI), Lane Home Furniture (Lane), and Morgan Fabrics Corporation (Morgan) within FTZ 158 in the greater Tupelo, Mississippi, area. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on June 17, 2016.

Bauhaus, HMRI, Lane, and Morgan currently have authority to conduct cut-and-sew activity using certain foreign micro-denier suede upholstery fabrics to produce upholstered furniture and related parts (upholstery cover sets) on a restricted basis (see B–29–2013, B–21–2013, B–28–2013, 78 FR 49254–49255, August 13, 2013; and, Board Order 1877, 78 FR 5773, January 28, 2013). The companies' authority allows for the production of upholstered furniture (chairs, seats, sofas, sleep sofas, and sectionals) with scopes of authority that only provide FTZ savings on a limited quantity of foreign origin, micro-denier suede upholstery fabric finished with a hot caustic soda solution process (*i.e.*, authorized fabrics). All foreign upholstery fabrics other than micro-denier suede finished with a hot caustic soda solution process (*i.e.*, unauthorized fabrics) used in Bauhaus, HMRI, Lane, and Morgan's production within FTZ 158 are subject to full customs duties.

The current request seeks to add certain polyurethane-type fabrics to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Bauhaus, HMRI, Lane, and Morgan from customs duty payments on the foreign-status fabrics used in export production. On domestic sales, Bauhaus, HMRI, Lane, and Morgan would be able to apply the finished upholstery cover set (*i.e.*, furniture part) or finished furniture duty rate (free) for the previously authorized fabrics and the additional fabrics (indicated below). Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The expanded scope of authority to admit foreign-status fabrics to FTZ 158 in nonprivileged foreign status (19 CFR 146.42) would only involve polyurethane fabrics backed with ground leather (5903.20.2500) and wet coagulation process 100 percent polyurethane coated fabrics (5903.20.2500), as detailed in the notification (duty rate: 7.5%). All other foreign, unauthorized upholstery fabrics used in the companies' production activity would continue to be admitted to the zone in domestic (duty paid) status.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is August 9, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: June 23, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–15631 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–11–2016]

Foreign-Trade Zone (FTZ) 230—Piedmont Triad Area, North Carolina; Authorization of Production Activity; United Chemi-Con, Inc. (Aluminum Electrolytic Capacitors); Lansing, North Carolina

On February 26, 2016, the Piedmont Triad Partnership, grantee of FTZ 230, submitted a notification of proposed production activity to the FTZ Board on behalf of United Chemi-Con, Inc., within Subzone 230A, in Lansing, North Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (81 FR 11512–11513, March 4, 2016). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: June 27, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–15626 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–44–2016]

Foreign-Trade Zone (FTZ) 44—Morris County, New Jersey; Notification of Proposed Production Activity; Givaudan Flavors Corporation (Flavor Products); East Hanover, New Jersey

The State of New Jersey, Department of State, grantee of FTZ 44, submitted a notification of proposed production activity to the FTZ Board on behalf of Givaudan Flavors Corporation (Givaudan), located in East Hanover, New Jersey. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on June 13, 2016.

A separate application for subzone designation at the Givaudan facility was submitted and will be processed under Section 400.31 of the Board's regulations. The facility is used for the production of flavor compounds. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Givaudan from customs duty payments on the foreign-status components used in export production. On its domestic sales, Givaudan would be able to choose the duty rates during customs entry procedures that apply to beverage preparations with alcohol, food articles containing sugar, concentrated orange oil, concentrated lemon oil, concentrated citrus oil, citrus oil blends, flavor preparations for food or drink without alcohol, flavor preparations for food or drink with alcohol, perfume bases and odoriferous substances other than food, drink or perfume bases (duty rate ranges from free to 17 cents/kg + 1.9%) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: benzaldehyde, vanillin, orange oil, concentrated orange oil, lemon oil, and concentrated lemon oil (duty rate ranges from 2.7% to 5.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is August 9, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: June 24, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–15628 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–42–2016]

Foreign-Trade Zone 158—Tupelo, Mississippi; Notification of Proposed Production Activity; Southern Motion, Inc.; Subzone 158G (Upholstered Furniture); Pontotoc and Baldwyn, Mississippi

The Greater Mississippi Foreign-Trade Zone, Inc., grantee of FTZ 158, submitted a notification of proposed production activity to the FTZ Board on behalf of Southern Motion, Inc. (SMI), for its facilities in Pontotoc and Baldwyn, Mississippi. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on June 17, 2016.

SMI currently has authority to conduct cut-and-sew activity using certain foreign micro-denier suede upholstery fabrics to produce upholstered furniture and related parts (upholstery cover sets) on a restricted basis (see B–45–2014, 79 FR 64167, October 28, 2014). SMI's authority allows for the production of upholstered furniture (chairs, seats, sofas, sleep sofas, and sectionals) for a five-year period, with a scope of authority that only provided FTZ savings on a limited quantity (6.0 million square yards per year) of foreign origin, micro-denier suede upholstery fabric finished with a hot caustic soda solution process (*i.e.,* authorized fabrics). All foreign upholstery fabrics other than micro-denier suede finished with a hot caustic soda solution process (*i.e.,* unauthorized fabrics) used in SMI's production within Subzone 158G are subject to full customs duties.

The current request seeks to add new foreign-status components and certain polyurethane-type fabrics to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt SMI from customs duty payments on the foreign-status fabrics and components used in export production. On its domestic sales, SMI would be able to apply the finished upholstery cover set (*i.e.,* furniture part) or finished furniture duty rate (free) for the previously authorized fabrics and the additional fabrics and components (indicated below). Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components sourced from abroad include: Linear actuators and motors; transformers; power adaptors; handset controllers; power cables; and, Y-cables (duty rate ranges from 1.6% to 2.8%). The expanded scope of authority to admit foreign-status fabrics to Subzone 158G would only involve polyurethane fabrics backed with ground leather (5903.20.2500) and wet coagulation process 100 percent polyurethane coated fabrics (5903.20.2500), as detailed in the notification (duty rate: 7.5%). All other foreign, unauthorized upholstery fabrics used in the production activity would continue to be admitted to the zone in domestic (duty paid) status.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is August 9, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz*.

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: June 20, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–15630 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–90–2016]

Foreign-Trade Zone 18—San Jose, California; Application for Subzone Expansion; Subzone 18E; Space Systems/Loral, LLC; Palo Alto, Menlo Park and Mountain View, California

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of San Jose, California, grantee of FTZ 18, requesting to expand Subzone 18E on behalf of Space Systems/Loral, LLC, located in Palo Alto, Menlo Park and Mountain View, California. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on June 22, 2016.

Subzone 18E was approved on June 16, 2006 (71 FR 37041, June 29, 2006) and currently consists of five sites: *Site 1* (28.4 acres)—3825, 3850 and 3875 Fabian Way, Palo Alto; *Site 2* (1 acre)—3977 and 3963 Fabian Way, Palo Alto; *Site 3* (5 acres)—1034–1036 and 1025 E. Meadow Circle, Palo Alto; *Site 4* (2.5 acres)—1205 and 1145 Hamilton Court, Menlo Park; and, *Site 5* (2.5 acres)—2288 Charleston Road, Mountain View. The applicant is now requesting authority to expand the subzone to include a new site (3.63 acres) located at 1989 Little Orchard Street, San Jose. No additional production authority is being requested at this time. The expanded subzone would be subject to the existing activation limit of FTZ 18.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is August 9, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to August 24, 2016.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz*.

For further information, contact Christopher Kemp at *christopher.kemp@trade.gov* or (202) 482–0862.

Dated: June 22, 2016.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2016–15629 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Civil Nuclear Trade Advisory Committee: Meeting of the Civil Nuclear Trade Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the Civil Nuclear Trade Advisory Committee (CINTAC).

DATES: The meeting is scheduled for Thursday, August 4, 2016, from 9:00 a.m. to 4:00 p.m. Eastern Daylight Time (EDT). The public session is from 3:00 p.m. to 4:00 p.m.

ADDRESSES: The meeting will be held in Room 1412, U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Ave. NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Chesebro, Office of Energy & Environmental Industries, International Trade Administration, Room 4053, 1401 Constitution Ave. NW., Washington, DC 20230. (Phone: 202–482–1297; Fax: 202–482–5665; email: *jonathan.chesebro@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background: The CINTAC was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), in response to an identified need for consensus advice from U.S. industry to the U.S. Government regarding the development and administration of programs to expand United States exports of civil nuclear goods and services in accordance with applicable U.S. laws and regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities will affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on May 13, 2016, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App. § 10(d)) that the portion of the meeting dealing with matters the disclosure of which would be likely to frustrate significantly implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. App. §§ 10(a)(1) and 10(a)(3), and that the portion of the meeting dealing with matters requiring disclosure of trade secrets and commercial or financial information as described in 5 U.S.C. 552b(c)(4) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. App. §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

Topics to be considered: The agenda for the Thursday, August 4, 2016 CINTAC meeting is as follows:

Closed Session (9:00 a.m.—3:00 p.m.)

1. Discussion of matters determined to be exempt from the provisions of the Federal Advisory Committee Act relating to public meetings found in 5 U.S.C. App. §§ (10)(a)(1) and 10(a)(3).

Public Session (3:00 p.m.—4:00 p.m.)

1. DOC's Civil Nuclear Trade Initiative (administered by the International Trade Administration (ITA)) Update.
2. Civil Nuclear Trade Promotion Activities Discussion.
3. Public comment period.

The meeting will be disabled-accessible. Public seating is limited and available on a first-come, first-served basis. Members of the public wishing to attend the meeting must notify Mr. Jonathan Chesebro at the contact information above by 5:00 p.m. EDT on Friday, July 29, 2016 in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time will be available for pertinent brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 30 minutes. Individuals wishing to reserve speaking time during the meeting must contact Mr. Chesebro and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5:00 p.m. EDT on Friday, July 29, 2016. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, ITA may conduct a lottery to determine the speakers. Speakers are requested to bring at least 20 copies of their oral comments for distribution to the participants and public at the meeting.

Any member of the public may submit pertinent written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to the Civil Nuclear Trade Advisory Committee, Office of Energy & Environmental Industries, Room 4053, 1401 Constitution Ave. NW., Washington, DC 20230. For consideration during the meeting, and to ensure transmission to the Committee prior to the meeting, comments must be received no later than 5:00 p.m. EDT on Friday, July 29, 2016. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

Dated: June 24, 2016.

Man Cho,

Director, Acting, Office of Energy and Environmental Industries.

[FR Doc. 2016–15479 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Health IT Trade Mission to Brazil September 26–30, 2016

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Department of Commerce, International Trade Administration (ITA) is organizing the 3rd Annual Health IT Trade Mission to Brazil from September 26–30, 2016. This mission is a continuation of two consecutive Health IT missions to Brazil and part of a sustained effort to help U.S. companies access the Brazilian Health IT market. Further, CS Brazil will work with leading Brazilian health media company, Live Media, and the Brazilian Health Informatics Association (SBIS) to organize an e-Health conference, which will be held in Sao Paulo at the same time as the trade mission. U.S. trade mission delegates will participate in the conference as part of the trade mission.

The purpose of the trade mission is to introduce U.S. firms to Brazil's rapidly expanding market for Health IT products, services and solutions and to assist U.S. companies in the pursuit of export opportunities in this sector. The trade mission to Brazil is designed for U.S. Health IT solution providers, particularly small- and medium-sized enterprises (SMEs), interested in long-term business opportunities in Brazil, as well as the trade associations/organizations that represent them. Target sectors holding high potential for U.S exporters include: Electronic Health Records (EHRs), Enterprise Resource Planning (ERP), Health IT interoperability system integration services, patient security, Health IT architecture design services, cyber security solutions, IoT solution providers, cloud solutions, clinical software, big data, clinical decision support, health analytics, health care transformation consulting, telehealth, smart mobile devices and mobile health applications, M2M connected devices, communication solutions, education of Health IT students and workforce training.

Trade mission delegates will participate in a five-day program, including technical visits to hospitals, roundtables and policy meetings with public health officials in Sao Paulo and Recife. In addition, on September 27, as part of the trade mission, delegates will participate in a one-day technology seminar at the e-Health Conference in Sao Paulo, thus giving the delegation heightened exposure to potential clients and partners from countries around the world. (Note that admission to the e-Health Conference September 27–28 is included in the Trade Mission fee). The delegates will also have networking opportunities to meet face-to-face with potential strategic partners, systems integrators, value added resellers (VAR's), hospital decision makers, planners and public health officials at the federal, state and city levels.

This mission supports President Obama's National Export Initiative (NEI). The mission will help new-to-market companies learn about the Brazilian Health IT market and make initial contacts. It will also support U.S. companies already doing business in Brazil to increase their footprint and deepen their business interests. The mission will also help participating firms and associations/organizations gain market insights, make industry contacts, implement business strategies, and advance specific projects, with the goal of increasing U.S. exports of products and services to Brazil.

Schedule

São Paulo, São Paulo, Brazil

Monday, September 26, 2016

- Hospital site and Technology Cluster visits (exclusively for trade mission delegates).

- Roundtable with public and private sector healthcare thought leaders (seminar is open to public).
- Networking reception, Sao Paulo (exclusively for trade mission delegates and invited Brazilian stakeholders).

(All day group bus transportation included).

Tuesday, September 27, 2016

- U.S. Health IT Business Seminar at e-Health Conference—opportunity for Trade Mission Delegates' Technology Presentations (seminar is open to public).
- Relationship Building dinner with hospitals, policy-makers, regulators and industry thought leaders (exclusively for trade mission delegates and invited Brazilian stakeholders).

(All day group bus transportation included).

Wednesday, September 28, 2016

- e-Health Conference—Health IT Business and Technology Seminar (seminar is open to public).
- Business networking opportunities and face-to-face meetings with key Health IT industry stakeholders at e-Health Conference for Health IT trade mission delegates exclusive to trade mission delegates.

(All day group bus transportation included).

- Delegation travels to Recife, Pernambuco.

Recife, Pernambuco, Brazil

Thursday, September 29, 2016

- Health IT Business and Technology Seminar (open to the public).
    - ○ U.S. delegates will participate in panel discussions with the following groups:
- Pernambuco Health Care Hospital Association Members.
- Recife Regional Hospitals.
- State and City Secretariats of Health.
- US Health IT Companies, Brazilian agents, distributors, integrators, VAR's.
    - ○ Lunch and coffee networking breaks.
- Networking reception with key regional healthcare stakeholders (exclusively for trade mission delegates and invited Brazilian stakeholders).

(All day group bus transportation included).

Friday, September 30, 2016

- Hospital site and Technology Cluster visits (exclusively for trade mission delegates).
- Round table with public and private sector healthcare thought leaders (exclusively for trade mission delegates).

(Group bus transportation to official events only, included).

Trade Mission concludes.

Web site: Please visit our official mission Web site for more information: *http://export.gov/trademissions/eg_main_023185.asp.*

Participation Requirements

All parties interested in participating in the trade mission must complete and submit an application package for consideration by the Department of Commerce (DOC). All applicants will be evaluated, on a rolling basis, on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. A minimum of six firms and/or trade associations or organizations will be selected to participate in the event from the applicant pool.

Fees and Expenses

After a firm or trade association/organization has been selected to participate in the event, a payment to the Department of Commerce in the form of a participation fee is required. The participation fee for the trade mission will be $2,450 for a small or medium-sized enterprise (SME) [1] and $2,975 for large firms and trade associations/organizations. The fee for each additional representative (SME or large firm or trade associations/organizations) is $1,075 and is subject to availability. Expenses for travel, lodging, meals, and incidentals will be the responsibility of each event delegate. Delegation members will be able to take advantage of U.S. Embassy rates for hotel rooms.

The participation fee for this mission includes admission to the e-Health Conference September 27–28, participation in the technology forum in Recife, September 29 and two airport bus transfers (to the São Paulo international airport and from the Recife airport to the designated hotel), as well as group ground transportation by bus to officially scheduled activities on September 26, 27, 28, 29 and 30.

Application

All interested firms and associations may register via the following link: *https://emenuapps.ita.doc.gov/ePublic/TM/6R18.*

Exclusions

The mission fee does not include any personal travel expenses such as lodging, most meals, local ground transportation (except for transportation to and from meetings, and airport transfers during the mission), and air transportation. Participants will, however, be able to take advantage of U.S. Government rates for hotel rooms. Electronic visas are required to participate on the mission, which are easily obtainable online. Applying for and obtaining such visas will be the responsibility of the mission participant. Government fees and processing expenses to obtain such visas are not included in the participation fee. However, the Department of Commerce will provide instructions to each participant on the procedures required to obtain necessary business visas.

Timeline for Recruitment and Applications

Trade mission recruitment will be conducted in an open and public manner, including, posting on the Commerce Department trade mission calendar and other Internet Web sites, email, press releases to general and trade media, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

Recruitment for the trade mission will begin immediately and conclude no later than September 9, 2016. Applications received after September 9, 2016, will be considered only if space and scheduling constraints permit.

The Department of Commerce will review applications and make selection decisions on a rolling basis beginning until the maximum of 20 delegates is selected.

Conditions for Participation

An applicant must sign and submit a completed application and supplemental application materials, including adequate information on the company's products and/or services, primary market objectives, and goals for participation. If an incomplete application form is submitted or the information and material submitted does not demonstrate how the applicant satisfies the participation criteria, the Department of Commerce may reject the application, request additional information, or take the lack of information into account when evaluating the application. Each applicant must also:

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[1] An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations (see *http://www.sba.gov/services/contractingopportunities/sizestandardstopics/index.html*). Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective November 24, 2015 (see *http://itacentral/myorg/gm/odg/osp/User%20Fees%20Resource%20Document%20Library/Marketing%20Flyer%20for%20Communicating%20with%20Clients%20(FY2016).pdf.*

- Identify whether the products and services it seeks to export through the mission are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have at least 51% U.S. content. In cases where the U.S. content does not exceed 50%, especially where the applicant intends to pursue investment in major project opportunities, the following factors, may be considered in determining whether the applicant's participation in the Trade Mission is in the U.S. national interest:
  - ○ U.S. materials and equipment content;
  - ○ U.S. labor content;
  - ○ Contribution to the U.S. technology base, including conduct of research and development in the United States;
  - ○ Repatriation of profits to the U.S. economy;
  - ○ Potential for follow-on business that would benefit the U.S. economy;

A trade association/organization applicant must certify to the above for all of the companies it seeks to represent on the mission.

An applicant must also certify that:

- The export of its goods, software, technology, and services would be in compliance with U.S. export control laws and regulations, including those administered by the Department of Commerce's Bureau of Industry and Security;
- It has identified any matter pending before any bureau or office of the Department of Commerce;
- It has identified any pending litigation (including any administrative proceedings) to which it is a party that involves the Department of Commerce;

It and its affiliates (1) have not and will not engage in the bribery of foreign officials in connection with its involvement in this Mission, and (2) maintain and enforce a policy that prohibits the bribery of foreign officials.

FOR FURTHER INFORMATION CONTACT:

U.S. Commercial Service Brazil, Everett Wakai, U.S. Commercial Service, Sao Paulo, Brazil, Tel: + 55 +11–3250–5402, Email: *everett.wakai@trade.gov.*

Jefferson Oliveira, U.S. Commercial Service, Sao Paulo, Brazil, Tel: + 55 +11–3250–5136, Email: *jefferson.oliveira@trade.gov.*

Patricia Marega, U.S. Commercial Service, Sao Paulo, Brazil, Tel: + 55 +11–3250–5482, Email: *patricia.marega@trade.gov.*

Frank Spector,

Trade Missions Program.

[FR Doc. 2016–15483 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–809]

Notice of Final Results of Antidumping Duty Changed Circumstances Review: Circular Welded Non-Alloy Steel Pipe From the Republic of Korea

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 13, 2016, the Department of Commerce (the Department) published the notice of initiation and preliminary results of the changed circumstances review of the antidumping duty order on circular welded non-alloy steel pipe (CWP) from the Republic of Korea.[1] In that notice, we preliminarily determined that Hyundai Steel Corporation (Hyundai Steel) is the successor-in-interest to Hyundai HYSCO (HYSCO) for purposes of determining antidumping duty cash deposits and liabilities. No interested party submitted comments on, or requested a public hearing to discuss, the initiation and preliminary results. For these final results, the Department continues to find that Hyundai Steel is the successor-in-interest to HYSCO.

DATES: Effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Joseph Shuler, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1293.

SUPPLEMENTARY INFORMATION:

Background

On February 24, 2016, Hyundai Steel informed the Department that, effective July 1, 2015, it merged with HYSCO, and requested that the Department conduct an expedited changed circumstances review under section 751(b) of the Act, 19 CFR 351.216(c), and 19 CFR 351.221(c)(3)(ii), to confirm that Hyundai Steel is the successor-in-interest to HYSCO for purposes of determining antidumping duty cash deposits and liabilities. On May 13, 2016, the Department initiated this changed circumstances review and published the notice of preliminary results, determining that Hyundai Steel is the successor-in-interest to HYSCO.

Scope of the Order

The merchandise subject to the order is circular welded non-alloy steel pipe and tube, of circular cross-section, not more than 406.4 millimeters (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipes and tubes and are intended for the low-pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air-conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing applications, such as for fence tubing, and as structural pipe tubing used for framing and as support members for reconstruction or load-bearing purposes in the construction, shipbuilding, trucking, farm equipment, and other related industries. Unfinished conduit pipe is also included in the order.

All carbon-steel pipes and tubes within the physical description outlined above are included within the scope of the order except line pipe, oil-country tubular goods, boiler tubing, mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished conduit.[2]

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090. Although the HTSUS numbers are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

All carbon-steel pipes and tubes within the physical description outlined above are included within the scope of the order except line pipe, oil-country tubular goods, boiler tubing, mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished conduit.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule

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[1] *See Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 81 FR 29840 (May 13, 2016) (*Initiation and Preliminary Results*).

[2] *See Final Negative Determination of Scope Inquiry on Certain Circular Welded Non-Alloy Steel Pipe and Tube from Brazil, the Republic of Korea, Mexico, and Venezuela,* 61 FR 11608 (March 21, 1996). In accordance with this determination, pipe certified to the API 5L line-pipe specification and pipe certified to both the API 5L line-pipe specifications and the less-stringent ASTM A-53 standard-pipe specifications, which falls within the physical parameters as outlined above, and entered as line pipe of a kind used for oil and gas pipelines, is outside of the scope of the AD order.

of the United States (HTSUS) numbers: 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090. Although the HTSUS numbers are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Final Results of Changed Circumstances Review

For the reasons stated in the *Initiation and Preliminary Results,* and because we received no comments from interested parties, the Department finds that Hyundai Steel is the successor-in-interest to HYSCO. As a result of this determination, we find that Hyundai Steel should receive the cash deposit rate assigned to HYSCO in the most recently completed review of the antidumping duty order on CWP from Korea.[3] Consequently, the Department will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced or exported by Hyundai Steel and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at 1.62 percent, which is the current antidumping duty cash-deposit rate for HYSCO. This cash deposit requirement shall remain in effect until further notice.

Dated: June 22, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–15471 Filed 6–29–16; 8:45 am]

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[3] *See Circular Welded Non-Alloy Steel Pipe from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2013–2014,* 81 FR 39908 (June 20, 2016).

DEPARTMENT OF COMMERCE

International Trade Administration

Subsea & Onshore Technology Trade Mission to Rio de Janeiro, Brazil October 19–21, 2016; Amendment

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Department of Commerce, International Trade Administration, is amending the Notice published at 80 FR 76657 (December 10, 2015), regarding the Subsea & Onshore Technology Trade Mission to Rio de Janeiro, Brazil October 19–21, 2016, to modify the selection process of applicants on a rolling basis starting immediately and until at least 10 participants are selected, with a maximum number of 15 participants. Applications received after July 25, 2016, will be considered only if space and scheduling constrains permit and participation fees must be paid by August 9, 2016.

SUPPLEMENTARY INFORMATION: Amendments to revise the selection process.

Background

It has been determined that the selection process of companies interested in participating in the mission will be vetted on a rolling basis. All applications will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria outlined under the conditions of participation clause. Applications for this Mission will be accepted through July 25, 2016 (and after that date if space remains and scheduling constraints permit). Interested U.S. companies and trade associations/organizations providing oil and gas equipment, technology, or services as well as U.S. companies seeking to enter the Brazilian market for the first time are encouraged to apply.

Contact Information

Ethel M. Azueta Glen, International Trade Specialist, Trade Missions, U.S. Department of Commerce, Washington, DC 20230, Tel: 202–482–5388, Fax: 202–482–9000, *Ethel.Glen@trade.gov.*

Frank Spector,

Director, Trade Missions Program.

[FR Doc. 2016–15481 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Healthcare Business Development Mission to China October 23–28, 2016

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Department of Commerce, International Trade Administration, is organizing an executive-led Healthcare Business Development Mission to China with an emphasis on the Sector. The mission is proposed at the Deputy Secretary level with participation from U.S. Department of Health and Human Services to ensure adequate access to Chinese government officials.

The purpose of the mission is open access to Chinese government health officials and to introduce U.S. firms and trade associations to the Chinese Healthcare market as well as assist U.S. companies to find business partners and export their products and services to China. The mission is intended to include representatives from U.S. companies and U.S. trade associations with members that provide high end, innovative medical devices (especially imaging), healthcare technology equipment, innovative pharmaceuticals, hospital management or senior care management solutions, and medical education or training, hospital cooperation (*i.e.* management and education), as well as pharmaceuticals and senior care segments.

Healthcare is an important issue for both the China. Today, China's annual healthcare spending is about $590.2 billion or 5.7% of its GDP. Commerce and health are not mutually exclusive, as workers become ill and as the cost of healthcare and insurance increases there is a direct impact on business through the loss of worker productivity and skilled workers, and reduced output. With fewer healthy workers earning incomes, businesses will also be harmed by decreased size and purchasing power of consumers. Families and individuals will be burdened with the impact of reduced incomes, increased health costs, and increased likelihood of long term care. As the world's two largest economies, how the two sides approach healthcare in the future has the potential to impact global macro-economic stability and future economic growth.

In recent years China has prioritized the reform of its healthcare system, to ensure citizens have good quality and affordable care, especially given the trends in the population and the increase in various health issues. The aging population, chronic disease and lack of fitness for children create challenges and burdens on establishing an effective healthcare system. Incidence of non-communicable disease (NCDs) such as cardiovascular disease, cancer and diabetes has rapidly increased. Economic growth is also impeded because NCDs hit workers in their prime years of productivity—creating long term chronic conditions, withdrawal from the workforce, diminished family resources and early death. Tackling the prevalence and significance of NCDs is challenging. The causes are rooted in the universal trends of aging and rapid urbanization, demographic factors which will only increase in the future.

Facing similar challenges and possessing common goals to achieve a successful healthcare ecosystem, the United States and China are well positioned to share experiences and find solutions to existing problems through uniting government and private sector forces at the intersection of commerce and healthcare. Areas of mutual collaboration in the healthcare could focus on improving patient access and services delivery, as well as areas of cooperation to benefit the health and lives of the population. As China reforms its' healthcare system and endeavors to create an innovative medical device and pharmaceutical industry it risks the alienation of foreign firms in the market. This trade mission will offer U.S. firms not only the opportunity to market their products and services, but also to explore ways that U.S. industry can support China's efforts to reform their healthcare system through win-win bilateral healthcare cooperation.

The trade mission will include one-on-one business appointments with pre-screened potential buyers, agents, distributors and joint venture partners; meetings with national and regional government officials, chambers of commerce, and business groups; and networking receptions for companies and trade associations representing companies interested in expansion into the Chinese markets. Meetings will be offered with government authorities (such as the National Health and Family Planning Commission, China Food and Drug Administration, Ministry of Human Resources and Social Services, and Ministry of Civil Affairs) that can address questions about policies, tariff rates, incentives, regulations, etc.

Schedule

Sunday, October 23

- Business Delegation arrives Beijing
- Business Delegation Meet and Greet/Icebreaker

Monday, October 24

- China Economic and Market briefing by U.S. Embassy staff on programs and opportunities in the Healthcare Sector
- Business Delegation Meeting with Vice Minister of National Health and Planning Commission
- Lunch hosted by Healthcare Association
- Business Delegation Meeting with Vice Minister of China Food and Drug Administration
- Business Delegation Meeting with Vice Minister of Ministry of Human Resources and Social Services

Tuesday, October 25

- Business Delegation Meeting with Vice Minister of Ministry of Civil Affairs
- Business Delegation Meeting with Commissioner of China Insurance Regulatory Commission
- Business Delegation Business-to-Business Meetings
- Mission Reception Hosted By U.S. Ambassador Baucus

Wednesday, October 26

- Airport Transfer to Beijing (PEK) Airport
- Morning Travel to Chongqing (post will recommend a specific flight, however flight is not included in the mission cost)
- Airport Transfer from Chongqing Airport
- Lunch Briefing by U.S. Consulate Chengdu staff on programs and opportunities in the Healthcare Sector
- Business Delegation Meeting with Chongqing Government Leadership
- Hospital Site Visit or Evening tourism event

Thursday, October 27

- Healthcare Association event (Healthcare Symposium, co-host with Chongqing Government)
- Business Delegation Networking Luncheon
- Business Delegation Business-to-Business Meetings
- CG-hosted Dinner for US companies and USGs

Friday, October 28

- Business Delegation Meeting with Chongqing Health Bureau
- Lunch Wrap-up Meeting
- Afternoon—Delegates free to depart

Web site

Please visit our official mission Web site for more information: *http://export.gov/trademissions/eg_main_023185.asp.*

Participation Requirements

All parties interested in participating in the trade mission must complete and submit an application package for consideration by the DOC. All applicants will be evaluated, on a rolling basis, on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. A minimum of 12 and maximum of 18 firms and/or trade associations or organizations will be selected to participate in the mission from the applicant pool.

Fees and Expenses

After a trade association/organization has been selected to participate on the mission, a payment to the Department of Commerce in the form of a participation fee is required. The participation fee for the Trade Mission will be $10,500 for a small or medium-sized enterprise (SME);[1] and $12,500 for a large firm and trade association/organization. The fee for each additional firm representative (large firm or SME/trade organization) is $3500. Expenses for travel, lodging, meals, and incidentals will be the responsibility of each mission participant. Interpreter and driver services can be arranged by the CS for additional cost. Delegation members will be able to take advantage of U.S. Embassy rates for hotel rooms.

Application

All interested firms and associations may register via the following link: *https://emenuapps.ita.doc.gov/ePublic/TM/7R0L.*

Exclusions

The mission fee does not include any personal travel expenses such as lodging, most meals, local ground transportation, except as stated in the proposed timetable, and air transportation from the U.S. to the mission sites and return to the United States. Business visas may be required. Government fees and processing expenses to obtain such visas are also not included in the mission costs. However, the U.S. Department of Commerce will provide instructions to each participant on the procedures required to obtain necessary business visas.

Timeline for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (*http://export.gov/trademissions*) and other internet Web sites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows. Recruitment for the mission will begin immediately and conclude no later than 1 July 2016. The

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[1] An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations (see *http://www.sba.gov/services/contractingopportunities/sizestandardstopics/index.html*). Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective May 1, 2008 (see *http://www.export.gov/newsletter/march2008/initiatives.html* for additional information).

U.S. Department of Commerce will review applications and make selection decisions on a rolling basis. Applications received after 1 July 2016, will be considered only if space and scheduling constraints permit.

Contacts

Mr. Dennis Simmons, Commercial Officer, U.S. Embassy Beijing | U.S. Department of Commerce, Beijing, China, Tel: +(86)1–8531–3445, *Dennis.Simmons@trade.gov*
Mr. Eric Hsu, Principal Commercial Officer, U.S. Consulate Chengdu | U.S. Department of Commerce, Chengdu, China, Tel: +(86) 28–8518–3992, *Eric.Hsu@trade.gov*
Ms. Yolinda Qu, International Trade Specialist, U.S. Department of Commerce, Office of China and Mongolia, Washington, DC, Tel: (202) 482–0007, *Yolinda.Qu@trade.gov*

Frank Spector,
Trade Missions Program.

[FR Doc. 2016–15486 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Information and Communication Technologies and Services Trade Mission to Singapore and Vietnam March 6–10, 2017

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY:

Mission Description

The United States Department of Commerce, International Trade Administration (ITA) is organizing an Informational and Technologies (ICT) Trade Mission to Singapore and Vietnam from March 6–10th, 2017. The purpose of the mission is to introduce U.S. firms to Singapore and Vietnam's rapidly expanding ICT sector, and to assist U.S. companies in pursuing export opportunities in this sector. The mission is designed for U.S. ICT companies. The mission also will help U.S. companies already doing business in Singapore and Vietnam increase their footprint and deepen their business interests. With the Administration's emphasis on enacting the Trans-Pacific Partnership, medium and long-term opportunities will continue for American companies that strategically position in these markets. The mission will not be an executive-led mission.

This trade mission focus on recruiting U.S. veteran-owned companies [1] [2] and others who play a significant role in information communication and telecom infrastructure development, by helping U.S. companies get ahead of their global competitors in the ASEAN markets that present excellent market opportunities in these sectors.

Target sectors holding high potential for U.S exporters include fixed and mobile telephone networks, Internet, satellites, broadcasting, Information Technology (IT) hardware and software, and in any sub-sector related to the telecommunications industry. Mission participants will benefit from country briefings, one-on-one appointments with prospective business contacts, and high-level meetings with government officials and business leaders.

The mission will help participating firms and associations/organizations gain market insights, make industry contacts, solidify business strategies, and advance specific projects, with the goal of increasing U.S. ICT exports. The mission will include market briefings, one-on-one business appointments with pre-screened potential buyers, agents, distributors, industry leaders, and joint venture partners; meetings with host governments; and networking events. Participating in an official U.S. industry delegation, rather than traveling on their own, will enhance the companies' ability to identify opportunities in Vietnam and Singapore.

Schedule

Arrive in Singapore March 4th and 5th

Monday, March 6, 2017

- Briefing by US Embassy Singapore officials
- Briefing by Singapore Government/ Industry officials
- One-on-one meetings with Singapore companies
- Networking Reception

Hanoi, Vietnam

Wednesday, March 8, 2017

- Briefing by U.S. Embassy officials
- Briefing by Vietnamese Government
- One-on-one meetings with Vietnamese companies
- Reception at Ambassador Residence

Thursday, March 9, 2017

Ho Chi Minh City

Friday, March 10, 2017

- Briefing by U.S. Consulate officials
- Briefing by Vietnamese Government
- One-on-one meetings with Vietnamese companies

Web site

Please visit our official mission Web site for more information: *http://export.gov/trademissions/eg_main_023185.asp.*

Participation Requirements

All parties interested in participating in the trade mission must complete and submit an application package for consideration by the U.S. Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. A minimum of ten firms and a maximum of 12 firms, service providers and/or trade associations/organizations will be selected from the applicant pool to participate in the trade mission.

Fees and Expenses

After an applicant has been selected to participate in the mission, a payment to the Department of Commerce in the form of a participation fee is required. Upon notification of acceptance to participate, those selected have 5 business days to submit payment or the acceptance may be revoked.

The participation fee for the trade mission to Singapore and Vietnam alone is $3,200.00 for small or medium-sized enterprises (SME) [3] and $5,300.00 for large firms and trade associations/organizations. The fee for each additional representative (large firm or SME or trade association/organization) is $750.00. The rate for additional/optional meetings in Ho Chi Minh City is not included, but would be the formal established GKS rates for one-day worth of scheduled meetings ($700).

Application

All interested firms and associations may register via the following link: *https://emenuapps.ita.doc.gov/ePublic/TM/7R0N.*

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[1] Formed by veterans of the U.S. Armed Forces, Vets Go Global is a team of U.S. Commercial Service international trade specialists dedicated to helping other U.S. veterans connect to business opportunities around the world. The Vets Go Global team is the main organizer of this trade mission.

[2] Despite the veteran-owned business focus, all companies are encouraged to apply. Recruitment will not be limited to veteran-owned businesses, and non-veteran-owned status will not determine eligibility and denial for the mission.

[3] An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations (see *http://www.sba.gov/services/contractingopportunities/sizestandardstopics/index.html*). Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective May 1, 2008 (see *http://www.export.gov/newsletter/march2008/initiatives.html* for additional information).

Exclusions

The mission fee does not include any personal travel expenses such as lodging, most meals, local ground transportation (except for transportation to and from meetings, and airport transfers during the mission), and air transportation. Participants will, however, be able to take advantage of U.S. Government rates for hotel rooms. Business or entry visas may be required to participate on the mission. Applying for and obtaining such visas will be the responsibility of the mission participant. Government fees and processing expenses to obtain such visas are not included in the participation fee. However, the Department of Commerce will provide instructions to each participant on the procedures required to obtain necessary business visas.

Timeframe for Recruitment and Application

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (*http://www.export.gov/trademissions/*) and other Internet Web sites, press releases to general and trade media, direct mail, broadcast fax, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows.

Recruitment for this mission will begin immediately and conclude no later than January 8, 2017. The U.S. Department of Commerce will review applications and make selection decisions on rolling basis. Applications received after January 8, 2017 will be considered only if space and scheduling constraints permit.

Contact Information

U.S. Contact

Ashish Vaid, International Trade Specialist, US & Foreign Commercial Service, 290 Broadway, Suite 1312, New York, NY 10007, t: 646–385–4503, *ashish.vaid@trade.gov.*

Dylan Daniels, International Trade Specialist, US & Foreign Commercial Service, 22 N. Front St., Suite 200, Memphis, TN 38103, t: 901–544–0930, *dylan.daniels@trade.gov.*

Singapore

Swee Hoon Chia, Senior Commercial Specialist, U.S. Department of Commerce, U.S. Commercial Service, U.S. Embassy Singapore, Tel: +65 6476–9037, Direct: +65 6476–9403, Fax: + 65 6476–9080, Email: *sweehoon.chia@trade.gov.*

Vietnam

Stuart Schaag, Senior Commercial Officer, U.S. Department of Commerce, U.S. Commercial Service, U.S. Consulate Embassy Hanoi, Tel: 84–4–3850–5199, Email: *Stuart.Schaag@trade.gov.*

Frank Spector,

Trade Mission Programs.

[FR Doc. 2016–15484 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Trade Mission to Central America in Conjunction With the Trade Americas—Business Opportunities in Central America Conference, March 26–31, 2017

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Department of Commerce, International Trade Administration is organizing a trade mission to Central America that will include the Trade Americas—Business Opportunities in Central America Conference in San Jose, Costa Rica on March 26–28, 2017.

U.S. trade mission participants will arrive in Costa Rica on or before March 26 to attend the opening reception for the Trade Americas—Business Opportunities in Central America Conference, which is also open to U.S. companies not participating in the trade mission. Trade mission participants will attend the Conference on March 27. Following the morning session of the conference, trade mission participants will participate in one-on-one consultations with U.S. and Foreign Commercial Service (US&FCS) Commercial Officers and/or Department of State Economic/Commercial Officers from the following U.S. Embassies in the region: Costa Rica, El Salvador, Honduras, Guatemala, Belize, Nicaragua, and Panama. The following day, March 28, trade mission participants will engage in business-to-business appointments with companies in Costa Rica. A limited number of trade mission participants will then have the option to travel to: El Salvador, Honduras, Guatemala, Belize, Nicaragua or Panama (choosing only one market) for optional additional business-to-business appointments based on recommendations from the US&FCS in those markets. Each business to business appointment will be with a pre-screened potential buyer, agent, distributor or joint-venture partner.

The Department of Commerce's Trade Americas—Business Opportunities in Central America Conference will focus on regional-specific sessions, market entry strategies, legal, logistics, and trade financing resources as well as pre-arranged one-on-one consultations with US&FCS Commercial Officers and/or Department of State Economic/Commercial Officers with expertise in commercial markets throughout the region.

This trade mission is open to U.S. companies from a cross section of industries with growing potential in Central America, but is focused on U.S. companies representing best prospects sectors such as construction equipment/road building machinery, renewable energy, automotive parts and accessories, and safety and security equipment.

The combination of the Trade Americas—Business Opportunities in Central America Conference and this trade mission, including its business-to-business matchmaking opportunities in Costa Rica and one other optional Central American country, will provide participants with access to substantive information on strategies for entering or expanding their business across the Central America region.

Schedule

March 26 Travel Day/Arrival to Costa Rica
 Registration, Market Briefings, and Networking Reception
March 27 Costa Rica
 Morning: Registration and Trade Americas—Business Opportunities in Central America Conference
 Afternoon: U.S. Embassy Officer Consultations
 Evening: Ambassador's Networking Reception
March 28 Costa Rica
 Business-to-Business Meetings
March 29 Travel Day

Optional

March 30 Business-to-Business Meetings in (Choice of one market):
 Option (A) Honduras
 Option (B) Guatemala
 Option (C) El Salvador
 Option (D) Belize
 Option (E) Nicaragua
 Option (F) Panama
March 31 Return to the U.S.

Web site: Please visit our official mission Web site for more information: *http://export.gov/trademissions/eg_main_023185.asp.*

Participation Requirements

All parties interested in participating in the U.S. Department of Commerce Trade Mission to Central America must complete and submit an application package for consideration by the Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below.

A minimum of 30 companies and/or trade associations will be selected to participate in the mission from the applicant pool on a first-come, first-served basis. The total number of U.S. companies that may be selected for each country will be limited as follows: 30 companies for Costa Rica, 10 companies for Guatemala, 10 companies for El Salvador; 4 companies for Belize; 12 companies for Honduras; 10 companies for Nicaragua; and 15 companies for Panama.

Additional participants may be accepted based on available space. U.S. companies and/or trade associations already doing business in or seeking business in Costa Rica, El Salvador, Belize, Guatemala, Honduras, Nicaragua and Panama for the first time may apply.

Fees and Expenses

After a company has been selected to participate in the mission, a payment to the Department of Commerce in the form of a participation fee is required.

- For business-to-business meetings in Costa Rica only (not traveling to an additional trade mission country), the participation fee will be $2,100 for a small or medium-sized enterprise (SME)* and $3,300 for a large firm.*
- For business-to-business meetings in Costa Rica and one other market, *i.e.* El Salvador OR Honduras OR Guatemala OR Belize OR Nicaragua, OR Panama, the participation fee will be $3,100 for a small or medium-sized enterprise (SME)* and $4,300 for a large firm.*

* An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations. Parent companies, affiliates, and subsidiaries will be considered when determining business size (See *https://www.sba.gov/content/what-are-small-business-size-standards*).

The above trade mission fees include the $450 participation fee for the Trade Americas—Business Opportunities in Central America Conference to be held in San Jose, Costa Rica on March 26–28, 2017.

An additional representative for both SMEs and large firms will require an additional fee of $450.

Application

All interested firms and associations may register via the following link: *https://emenuapps.ita.doc.gov/ePublic/TM/7R0M.*

Exclusions

The mission fee does not include any personal travel expenses such as lodging, most meals, local ground transportation (except for transportation to and from meetings, and airport transfers during the mission), and air transportation. Participants will, however, be able to take advantage of U.S. Government rates for hotel rooms. Electronic visas are required to participate on the mission, which are easily obtainable online. Applying for and obtaining such visas will be the responsibility of the mission participant. Government fees and processing expenses to obtain such visas are not included in the participation fee. However, the Department of Commerce will provide instructions to each participant on the procedures required to obtain necessary business visas.

Timeline for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (*http://export.gov/trademissions*) and other Internet Web sites, press releases to the general and trade media, direct mail, broadcast fax, notices by industry trade associations, and other multiplier groups and announcements at industry meetings, symposia, conferences, and trade shows.

Recruitment for the mission will begin immediately and conclude no later than January 31, 2017. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis beginning 14 days after publication of this **Federal Register** notice, until the minimum of 30 participants is selected. After January 31, 2017, applications will be considered only if space and scheduling constraints permit.

Conditions for Participation

- An applicant must submit a completed and signed mission application and supplemental application materials, including adequate information on the company's products and/or services, primary market objectives, and goals for participation. Applicant should specify in their application and supplemental materials which trade mission stops they are interested in participating in. If the Department of Commerce receives an incomplete application, the Department may reject the application, request additional information, or take the lack of information into account when evaluating the applications.
- Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the U.S., or, if not, marketed under the name of a U.S. firm and have at least 51% U.S. content of the value of the finished product or service. In the case of a trade association or trade organization, the applicant must certify that, for each company to be represented by the trade association or trade organization, the products and services the represented company seeks to export are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have at least 51% U.S. content.

The following criteria will be evaluated in selecting participants:

- Suitability of a firm's or service provider's (or in the case of a trade association/organization, represented firm or service provider's) products or services to these markets.
- Firm's or service provider's (or in the case of a trade association/organization, represented firm or service provider's) potential for business in the markets, including likelihood of exports resulting from the mission.
- Consistency of the firm's or service provider's (or in the case of a trade association/organization, represented firm or service provider's) goals and objectives with the stated scope of the mission.

Diversity of company size, sector or subsector, and location may also be considered during the review process.

Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and not considered during the selection process.

FOR FURTHER INFORMATION CONTACT: Jessica Gordon, International Trade Specialist, U.S. Export Assistance Center—Jackson, MS, *Jessica.Gordon@trade.gov*, Tel: 601–373–0784.

Diego Gattesco, Director, U.S. Export Assistance Center—Wheeling, WV, *Diego.Gattesco@trade.gov*, Tel: 304–243–5493.

Aileen Nandi, Regional Senior Commercial Officer, U.S. Commercial Service—El Salvador, *Aileen.Nandi@trade.gov.*

Abby Daniell, Commercial Director, U.S. Commercial Service—Costa Rica, *Abby.Daniell@trade.gov.*

Frank Spector,

Trade Missions Program.

[FR Doc. 2016–15485 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket Number: 160603485–6485–01]

Award Competitions for Hollings Manufacturing Extension Partnership (MEP) Centers in the States of Delaware, Hawaii, Iowa, Kansas, Maine, Mississippi, New Mexico, Nevada, North Dakota, South Carolina and Wyoming

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce (DoC).

ACTION: Notice of funding availability.

SUMMARY: NIST invites applications from eligible organizations in connection with NIST's funding up to eleven (11) separate MEP cooperative agreements for the operation of MEP Centers in the designated States' service areas and in the funding amounts identified in the Funding Availability section of this notice. NIST anticipates awarding one (1) cooperative agreement for each of the identified States. The objective of this announcement by the MEP Program is to provide manufacturing extension services to primarily small and medium-sized manufacturers within the States designated in the Funding Availability section of this notice. The selected organizations will become part of the MEP national system of extension service providers, currently located throughout the United States and Puerto Rico.

DATES: Electronic applications must be received no later than 11:59 p.m. Eastern Time on Tuesday, September 27, 2016. Paper applications will not be accepted. Applications received after the deadline will not be reviewed or considered. The approximate start date for awards under this notice and the corresponding FFO is expected to be April 1, 2017.

ADDRESSES: Applications must be submitted electronically through *www.grants.gov.* NIST will not accept applications submitted by mail, facsimile, or by email.

FOR FURTHER INFORMATION CONTACT: Administrative, budget, cost-sharing, and eligibility questions and other programmatic questions should be directed to Diane Henderson at Tel: (301) 975–5105; Email: *mepffo@nist.gov;* Fax: (301) 963–6556. Grants Rules and Regulation questions should be addressed to: Matthew Jones, Grants Management Division, National Institute of Standards and Technology, 100 Bureau Drive, Stop 1650, Gaithersburg, MD 20899–1650; Tel: (301) 975–3698; Email: *matthew.jones@nist.gov;* Fax: (301) 975–6368. For technical assistance with *Grants.gov* submissions contact Christopher Hunton at Tel: (301) 975–5718; Email: *grants@nist.gov;* Fax: (301) 975–8884. Questions submitted to NIST/MEP may be posted as part of an FAQ document, which will be periodically updated on the MEP Web site at *http://nist.gov/mep/ffo-state-competitions-04.cfm.*

SUPPLEMENTARY INFORMATION:

Electronic access: Applicants are strongly encouraged to read the corresponding FFO announcement available at *www.grants.gov* for complete information about this program, including all program requirements and instructions for applying electronically. Paper applications or electronic applications submitted other than through *www.grants.gov* will not be accepted. The FFO may be found by searching under the Catalog of Federal Domestic Assistance Name and Number provided below.

System Award Management registration required: When developing your submission timeline, please keep in mind that (1) all applicants are required to have a current registration in the System for Award Management (*SAM.gov*); (2) the free annual registration process in the electronic System for Award Management (*SAM.gov*) may take between three and five business days, or as long as more than two weeks; (3) applicants submitting electronic applications are required to have a current registration in *Grants.gov*; and (4) applicants will receive a series of email messages from *Grants.gov* over a period of up to two business days before learning whether a Federal agency's electronic system has received its application. Please note that a Federal assistance award cannot be issued if the designated recipient's registration in the *SAM.gov* is not current at the time of the award.

Authority: 15 U.S.C. 278k, as implemented in 15 CFR part 290.

Catalog of Federal Domestic Assistance Name and Number: Manufacturing Extension Partnership—11.611.

Webinar Information Session: NIST/MEP will hold one or more webinar information sessions for organizations that are considering applying to this opportunity. These webinars will provide general information regarding MEP and offer general guidance on preparing proposals. NIST/MEP staff will be available on the webinars to answer general questions. During the webinars, proprietary technical discussions about specific project ideas will not be permitted. Also, NIST/MEP staff will not critique or provide feedback on any specific project ideas during the webinars or at any time before submission of a proposal to MEP. However, NIST/MEP staff will provide information about the MEP eligibility and cost sharing requirements, evaluation criteria and selection factors, selection process, and the general characteristics of a competitive MEP proposal during this webinar, and by phone and email. The webinars will be held approximately fifteen (15) to thirty (30) business days after posting of the corresponding FFO. The exact dates and times of the webinars will be posted on the MEP Web site at *http://nist.gov/mep/ffo-state-competitions-04.cfm.* The webinars will be recorded, and a link to the recordings will be posted on the MEP Web site. In addition, the webinar presentations will be available on the MEP Web site. Organizations wishing to participate in one or more webinar(s) must sign up by emailing *mepffo@nist.gov.* Participation in the webinars is not required in order for an organization to submit an application pursuant to this notice and the corresponding FFO.

Program Description: NIST invites applications from eligible organizations in connection with NIST's funding up to eleven (11) separate cooperative agreements for the operation of MEP Centers in the designated States' service areas and in the funding amounts identified in Section II.2. of the corresponding FFO. NIST anticipates awarding one (1) cooperative agreement for each of the identified States. The objective of this announcement by the MEP Program is to provide manufacturing extension services to primarily small and medium-sized manufacturers within the States designated in the Funding Availability section of this notice. The selected organizations will become part of the MEP national system of extension service providers, located throughout the United States and Puerto Rico.

The MEP program is not a Federal research and development program. It is not the intent of the program that awardees will perform systematic research.

To learn more about the MEP program, please go to *http://www.nist.gov/mep/.*

Funding Availability: NIST anticipates funding up to eleven (11) MEP Center awards with an initial five-year period of performance in accordance with the multi-year funding policy described below and in Section II.3. of the corresponding FFO. Funding for the awards listed below and in the corresponding FFO is contingent upon the availability of appropriated funds.

The table below lists the eleven (11) States identified for funding as part of this notice and the corresponding FFO and the estimated amount of funding available for each:

MEP Center location and assigned geographical service area (by state)	Anticipated annual federal funding for each year of the award	Total federal funding for 5 year award period
Delaware	$500,000	$2,500,000
Hawaii	500,000	2,500,000
Iowa	1,859,206	9,296,030
Kansas	1,864,950	9,324,750
Maine	863,522	4,317,610
Mississippi	1,003,782	5,018,910
New Mexico	1,360,802	6,804,010
Nevada	756,001	3,780,005
North Dakota	500,000	2,500,000
South Carolina	2,268,003	11,340,015
Wyoming	500,000	2,500,000

Applicants may propose annual Federal funding amounts that are different from the anticipated annual Federal funding amounts set forth in the above table, provided that the total amount of Federal funding being requested by an applicant does not exceed the total amount of Federal funding for the five-year award period as set forth in the above table. For example, if the anticipated annual Federal funding amount for an MEP Center is $500,000 and the total Federal funding amount for the five-year award period is $2,500,000, an applicant may propose Federal funding amounts greater, less than, or equal to $500,000 for any year or years of the award, so long as the total amount of Federal funding being requested by the applicant for the entire five-year award period does not exceed $2,500,000.

Multi-Year Funding Policy. When an application for a multi-year award is approved, funding will usually be provided for only the first year of the project. Recipients will be required to submit detailed budgets and budget narratives prior to the award of any continued funding. Continued funding for the remaining years of the project will be awarded by NIST on a non-competitive basis, and may be adjusted higher or lower from year-to-year of the award, contingent upon satisfactory performance, continued relevance to the mission and priorities of the program, and the availability of funds. Continuation of an award to extend the period of performance and/or to increase or decrease funding is at the sole discretion of NIST.

Potential for Additional 5 Years. Initial awards issued pursuant to this notice and the corresponding FFO are expected to be for up to five (5) years with the possibility for NIST to renew the award, on a non-competitive basis, for an additional 5 years at the end of the initial award period. The review processes described in 15 CFR 290.8 will be used as part of the overall assessment of the recipient, consistent with the potential long-term nature and purpose of the program. In considering renewal for a second five-year, multi-year award term, NIST will evaluate the results of the annual reviews and the results of the 3rd Year peer-based Panel Review findings and recommendations as set forth in 15 CFR 290.8, as well as the Center's progress in addressing findings and recommendations made during the various reviews. The full process is expected to include programmatic, policy, financial, administrative, and responsibility assessments, and the availability of funds, consistent with Department of Commerce and NIST policies and procedures in effect at that time.

Kick-Off Conferences

Each recipient will be required to attend a kick-off conference, which will be held within 30 days post start date of award, to help ensure that the MEP Center operator has a clear understanding of the program and its components. The kick-off conference will take place at NIST/MEP headquarters in Gaithersburg, MD, during which time NIST will: (1) Orient MEP Center key personnel to the MEP program; (2) explain program and financial reporting requirements and procedures; (3) identify available resources that can enhance the capabilities of the MEP Center; and (4) negotiate and develop a detailed three-year operating plan with the recipient. NIST/MEP anticipates an additional set of site visits at the MEP Center and/or telephonic meetings with the recipient to finalize the three-year operating plan.

The kick-off conference will take up to approximately three days and must be attended by the MEP Center Director, along with up to two additional MEP Center employees. Applicants must include travel and related costs for the kick-off conference as part of the budget for year one (1), and these costs should be reflected in the SF-424A form. (*See* Section IV.2.a.(2) of the corresponding FFO.) These costs must also be reflected in the budget table and budget narrative for year 1, which is submitted as part of the budget tables and budget narratives section of the Technical Proposal. (*See* Section IV.2.a.(6).(e). of the corresponding FFO.) Representatives from key subrecipients and other key strategic partners may attend the kick-off conference with the prior written approval of the Grants Officer. Applicants proposing to have key subrecipients and/or other key strategic partners attend the kick-off conference should clearly indicate so as part of the budget narrative for year one of the project.

MEP System-Wide Meetings

NIST/MEP typically organizes system-wide meetings approximately four times a year in an effort to share best practices, new and emerging trends, and additional topics of interest. These meetings are rotated throughout the United States and typically involve 3–4 days of resource time and associated travel costs for each meeting. The MEP Center Director must attend these meetings, along with up to two additional MEP Center employees.

Applicants must include travel and related costs for four quarterly MEP system-wide meetings in each of the five (5) project years (4 meetings per year; 20 total meetings over five-year award period). These costs must be reflected in the SF–424A form (*see* Section IV.2.a.(2). of the corresponding FFO). These costs must also be reflected in the budget tables and budget narratives for each of the project's five (5) years, which are submitted in the budget tables and budget narratives section of the Technical Proposal. (*See* Section IV.2.a.(6).(e). of the corresponding FFO.) A suggested budget summary table and narrative template for Year 1 and budget summary table for Years 2–5 are available on the MEP Web site, *http://nist.gov/mep/ffo-state-competitions-04.cfm.*

Cost Share or Matching Requirement: Non-Federal cost sharing of at least 50 percent of the total project costs is required for each of the first through the third year of the award, with an increasing minimum non-Federal cost share contribution beginning in year 4 of the award as follows:

Award year	Maximum NIST share	Minimum non-federal share
1–3	1/2	1/2
4	2/5	3/5
5 and beyond	1/3	2/3

Non-Federal cost sharing is that portion of the project costs not borne by the Federal Government. The applicant's share of the MEP Center expenses may include cash, services, and third party in-kind contributions, as described at 2 CFR 200.306, as applicable, and in the MEP program regulations at 15 CFR 290.4(c). No more than 50% of the applicant's total non-Federal cost share for any year of the award may be from third party in-kind contributions of part-time personnel, equipment, software, rental value of centrally located space, and related contributions, per 15 CFR 290.4(c)(5). The source and detailed rationale of the cost share, including cash, full- and part-time personnel, and in-kind donations, must be documented in the budget tables and budget narratives submitted with the application and will be considered as part of the review under the evaluation criterion found in the Evaluation Criteria section of this notice and in Section V.1.c.ii. of the corresponding FFO.

Recipients must meet the minimum non-Federal cost share requirements for each year of the award as identified in the chart above. For purposes of the MEP program, "program income" (as defined in 2 CFR 200.80, as applicable) generated by an MEP Center may be used by a recipient towards the required non-Federal cost share under an MEP award.

As with the Federal share, any proposed costs included as non-Federal cost sharing must be an allowable/eligible cost under this program and under the Federal cost principles set forth in 2 CFR part 200, subpart E. Non-Federal cost sharing incorporated into the budget of an approved MEP cooperative agreement is subject to audit in the same general manner as Federal award funds. *See* 2 CFR part 200, subpart F.

As set forth in Section IV.2.a.(7). of the corresponding FFO, a letter of commitment is required from an authorized representative of the applicant, stating the total amount of cost share to be contributed by the applicant towards the proposed MEP Center. Letters of commitment for all other third-party sources of non-Federal cost sharing identified in a proposal are not required, but are strongly encouraged.

Eligibility: The eligibility requirements set forth here and in Section III.1. of the corresponding FFO will be used in lieu of and to the extent they are inconsistent with will supersede those given in the MEP regulations found at 15 CFR part 290, specifically 15 CFR 290.5(a)(1). Each applicant for and recipient of an MEP award must be a U.S.-based nonprofit institution or organization. For the purpose of this notice and the corresponding FFO, nonprofit institutions include public and private nonprofit organizations, nonprofit or State colleges and universities, public or nonprofit community and technical colleges, and State, local or Tribal governments. Existing MEP awardees and new applicants that meet the eligibility criteria set forth here and in Section III.1. of the corresponding FFO may apply. An eligible organization may work individually or may include proposed subawards to eligible organizations or proposed contracts with any other organization as part of the applicant's proposal, effectively forming a team. However, as discussed in Section I.4. of the corresponding FFO, NIST generally will not fund applications that propose an organizational or operational structure that, in whole or in part, delegates or transfers to another person, institution, or organization the applicant's responsibility for MEP Core Management and Oversight functions. In addition, the applicant must have or propose an Oversight Board or Advisory Committee and Governance structure or plan for establishing a board structure within 90 days from the award start date (Refer to Section I.3. of the corresponding FFO). This program requires non-Federal cost share of at least 50 percent of the total allowable project costs for the first through the third years of operation, with increasing minimum non-Federal cost share requirements beginning in year four (4) of the award. *See* Cost Share or Matching Requirement section of this notice and Section III.2. of the corresponding FFO for more information on the non-Federal cost sharing requirements under MEP awards.

Application Requirements: Applications must be submitted in accordance with the requirements set forth in Section IV. of the corresponding FFO announcement, which are in lieu of and to the extent they are inconsistent with will supersede any application requirements set forth in 15 CFR 290.5. *See specifically* Sections IV.2.a.(1)., IV.2.a.(2)., and IV.2.a.(7). in the Full Announcement Text of the corresponding FFO.

Application/Review Information: The evaluation criteria, selection factors, and review and selection process provided in this section and in Section V. of the corresponding FFO will be used for this competition in lieu of and to the extent they are inconsistent with will supersede those provided in the MEP regulations found at 15 CFR part 290, specifically 15 CFR 290.6 and 290.7.

Evaluation Criteria: The evaluation criteria that will be used in evaluating applications and assigned weights, with a maximum score of 100, are listed below.

a. Project Narrative. (40 points; Sub-criteria i through iv will be weighted equally) NIST/MEP will evaluate the extent to which the applicant's Project Narrative demonstrates how the applicant's methodology will efficiently and effectively establish an MEP Center and provide manufacturing extension services to primarily small and medium-sized manufacturers in the applicable State-wide geographical service area identified in Section II.2. of the corresponding FFO. Reviewers will consider the following topics when evaluating the Project Narrative:

i. Center Strategy. Reviewers will assess the applicant's strategy proposed for the Center to deliver services that meet manufacturers' needs, generate client impacts (*e.g.,* cost savings, increased sales, etc.), and support a strong manufacturing ecosystem. Reviewers will assess the quality with which the applicant:

- Incorporates the market analysis described in the criterion set forth in paragraph a.ii.(1) below and Section V.1.a.ii.(1). of the corresponding FFO to inform strategies, products and services;
- defines a strategy for delivering services that balances market penetration with impact and revenue generation, addressing the needs of manufacturers, with an emphasis on the small and medium-sized manufacturers;
- defines the Center's existing and/or proposed roles and relationships with other entities in the State's manufacturing ecosystem, including State, regional, and local agencies, economic development organizations and educational institutions such as universities and community or technical colleges, industry associations, and other appropriate entities;
- plans to engage with other entities in Statewide and/or regional advanced manufacturing initiatives; and
- supports achievements of the MEP mission and objectives while also satisfying the interests of other stakeholders, investors, and partners.

ii. Market Understanding. Reviewers will assess the strategy proposed for the Center to define the target market, understand the needs of manufacturers (especially Small and Medium Enterprises (SMEs)), and to define appropriate services to meet identified needs. Reviewers will evaluate the proposed approach for regularly updating this understanding through the five years. The following sub-topics will be evaluated and given equal weight:

(1) Market Segmentation. Reviewers will assess the quality and extent of the applicant's market segmentation strategy including:

- Segmentation of company size, geography, and industry priorities including some consideration of rural, start-up (a manufacturing establishment that has been in operation for five years or less) and/or very small manufacturers as appropriate to the state;
- alignment with state and/or regional initiatives; and
- other important factors identified by the applicant.

(2) Needs Identification and Product/Service Offerings. Reviewers will assess the quality and extent of the applicant's proposed needs identification and proposed products and services for both sales growth and operational improvement in response to the applicant's market segmentation and understanding assessed by reviewers under paragraph a.ii.(1) above and Section V.1.a.ii.(1) of the corresponding FFO. Of particular interest is how the applicant would leverage new manufacturing technologies, techniques and processes usable by small and medium-sized manufacturers. Reviewers will also consider how an applicant's proposed approach will support a job-driven training agenda with manufacturing clients. (To learn more about the White House job-driven training agenda, please go to: *https://www.whitehouse.gov/sites/default/files/docs/ready_to_work_factsheet.pdf.*)

iii. Business Model. Reviewers will assess the quality, feasibility and potential efficacy and efficiency of the applicant's proposed business model for the Center as provided in the Project Narrative, Qualifications of the Applicant; Key Personnel, Organizational Structure and Management, and the Budget Tables and Budget Narratives sections of its Technical Proposal, submitted under section IV.2.a.(6). of the corresponding FFO, and the likelihood that the proposed business model will result in the Center's ability to successfully execute the strategy evaluated under criterion set forth in paragraph a.1. above and Section V.1.a.i. of the corresponding FFO, based on the market understanding evaluated under criterion set forth in paragraph a.ii. above and Section V.1.a.ii. of the corresponding FFO. The following sub-topics will be evaluated and given equal weight:

(1) Outreach and Service Delivery to the Market. Reviewers will assess the extent to which the proposed Center is organized to:

- Identify, reach and provide proposed services to key market segments and individual manufacturers described above;
- work with a manufacturer's leadership in strategic discussions related to new technologies, new products and new markets; and
- leverage the applicant's past experience in working with small and medium-sized manufacturers as a basis for future programmatic success.

(2) Partnership Leverage and Linkages. Reviewers will assess the extent to which the proposed Center will make effective use of resources or partnerships with third parties such as industry, universities, community/technical colleges, nonprofit economic development organizations, and Federal, State and Local Government Agencies in the Center's business model.

iv. Performance Measurement and Management. Reviewers will assess the extent to which the applicant will use a systematic approach to measuring and managing performance including the:

- Quality and extent of the applicant's stated goals, milestones and outcomes described by operating year (year 1, year 2, etc.);
- applicant's utilization of client-based business results important to stakeholders in understanding program impact; and
- depth of the proposed methodology for program management and internal evaluation likely to ensure effective operations and oversight for meeting program and service delivery objectives.

b. Qualifications of the Applicant; Key Personnel, Organizational Structure and Management; and Oversight Board or Advisory Committee and Governance (30 points; Sub-criteria i and ii will be weighted equally). Reviewers will assess the ability of the key personnel, the applicant's management structure and Oversight Board or Advisory Committee and Governance to deliver the program and services envisioned for the Center. Reviewers will consider the following topics when evaluating the qualifications of the applicant and of program management:

i. Key Personnel, Organizational Structure and Management. Reviewers will assess the extent to which the:

- Proposed key personnel have the appropriate experience and education in manufacturing, outreach, program management and partnership development to support achievements of the MEP mission and objectives;
- proposed management structure and organizational roles are aligned to plan, direct, monitor, organize and control the monetary resources of the proposed center to achieve its business

objectives (Refer to Section I.4. of the corresponding FFO);

- proposed organizational structure flows logically from the specified approach to the market and products and service offerings; and
- proposed field staff structure sufficiently supports the geographic concentrations and industry targets for the region.

ii. Oversight Board or Advisory Committee and Governance. Reviewers will assess the extent to which the:

- Proposed Oversight Board or Advisory Committee and its operations are complete, appropriate and will meet the program's objectives at the time of award, or, if such an Oversight Board or Advisory Committee does not exist at the time of application or is not expected to meet these requirements at the time of award, the extent to which the proposed plan for developing and implementing such an Oversight Board or Advisory Committee within 90 days of award start date (expected to be April 1, 2017) is feasible. (Refer to Section I.3. of the corresponding FFO).
- Oversight Board or Advisory Committee and Governance is engaged with overseeing and guiding the Center and supports its own development through a schedule of regular meetings, and processes ensuring Oversight Board or Advisory Committee involvement in strategic planning, recruitment, selection and retention of board members, board assessment practices and board development initiatives (Refer to Section I.3. of the corresponding FFO).

c. Budget and Financial Plan. (30 points; Sub-criteria i and ii will be weighted equally) Reviewers will assess the suitability and focus of the applicant's five (5) year budget. The application will be assessed in the following areas:

i. Budget. Reviewers will assess the extent to which:

- The proposed financial plan is aligned to support the execution of the proposed Center's strategy and business model over the five (5) year project plan;
- the proposed projections for income and expenditures are appropriate for the scale of services that are to be delivered by the proposed Center and the service delivery model envisioned within the context of the overall financial model over the five (5) year project plan;
- a reasonable ramp-up or scale-up scope and budget has the Center fully operational by the 4th year of the project; and
- the proposal's narrative for each of the budgeted items explains the rationale for each of the budgeted items, including assumptions the applicant used in budgeting for the Center.

ii. Quality of the Financial Plan for Meeting the Award's Non-Federal Cost Share Requirements over 5 Years. Reviewers will assess the quality of and extent to which the:

- Applicant clearly describes the total level of cost share and detailed rationale of the cost share, including cash and in-kind, in their proposed budget.
- applicant's funding commitments for cost share are documented by letters of support from the applicant, proposed sub-recipients and any other partners identified and meet the basic matching requirements of the program;
- applicant's cost share meets basic requirements of allowability, allocability and reasonableness under applicable Federal costs principles set forth in 2 CFR 200, subpart E;
- applicant's underlying accounting system is established or will be established to meet applicable Federal costs principles set forth in 2 CFR 200, subpart E; and
- the overall proposed financial plan is sufficiently robust and diversified so as to support the long term sustainability of the Center throughout the five (5) years of the project plan.

Selection Factors: The Selection Factors for this notice as set forth here and in Section V.3. of the corresponding FFO are as follows:

a. The availability of Federal funds;

b. Relevance of the proposed project to MEP program goals and policy objectives;

c. Reviewers' evaluations, including technical comments;

d. The need to assure appropriate distribution of MEP services within the designated State;

e. Whether the project duplicates other projects funded by DoC or by other Federal agencies; and

f. Whether the application complements or supports other Administration priorities, or projects supported by DoC or other Federal agencies, such as but not limited to the National Network for Manufacturing Innovation and the Investing in Manufacturing Communities Partnership.

Review and Selection Process

Proposals, reports, documents and other information related to applications submitted to NIST and/or relating to financial assistance awards issued by NIST will be reviewed and considered by Federal employees, Federal agents and contractors, and/or by non-Federal personnel who enter into nondisclosure agreements covering such information as set forth here and in Section V.2. of the corresponding FFO, which will be used for this competition in lieu of and to the extent they are inconsistent with will supersede the review and selection process provided in the MEP regulations found at 15 CFR part 290, specifically 15 CFR 290.7.

(1) Initial Administrative Review of Applications. An initial review of timely received applications will be conducted to determine eligibility, completeness, and responsiveness to this notice and the corresponding FFO and the scope of the stated program objectives. Applications determined to be ineligible, incomplete, and/or non-responsive may be eliminated from further review. However, NIST, in its sole discretion, may continue the review process for an application that is missing non-substantive information that can easily be rectified or cured.

(2) Full Review of Eligible, Complete, and Responsive Applications. Applications that are determined to be eligible, complete, and responsive will proceed for full reviews in accordance with the review and selection processes below. Eligible, complete and responsive applications will be grouped by the State in which the proposed MEP Center is to be established. The applications in each group will be reviewed by the same reviewers and will be evaluated, reviewed, and selected as described below in separate groups.

(3) Evaluation and Review. Each application will be reviewed by at least three technically qualified individual reviewers who will evaluate each application based on the evaluation criteria (*see* Evaluation Criteria section of this notice and Section V.1. of the corresponding FFO). Applicants may receive written follow-up questions in order for the reviewers to gain a better understanding of the applicant's proposal. Each reviewer will provide a written technical assessment against the evaluation criteria and based on that assessment will assign each application a numeric score, with a maximum score of 100. If a non-Federal reviewer is used, the reviewers may discuss the applications with each other, but scores will be determined on an individual basis, not as a consensus.

Applicants whose applications receive an average score of 70 or higher out of 100 will be deemed finalists. If deemed necessary, finalists will be invited to participate with reviewers in a conference call and/or a video conference, and/or finalists will be invited to participate in a site visit that will be conducted by the same reviewers at the applicant's location. In any event, if there are two (2) or more finalists within a state, conference calls, video conferences or site visits will be conducted with each finalist. Finalists will be reviewed and evaluated, and reviewers may revise their assigned numeric scores based on the evaluation criteria (*see* Evaluation Criteria section of this notice and Section V.1. of the corresponding FFO) as a result of the conference call, video conference, and/or site visit.

(4) Ranking and Selection. Based upon an average of the technical reviewers' final scores, an adjectival rating will be assigned to each application in accordance with the following scale:

Fundable, Outstanding (91–100 points);

Fundable, Very Good (81–90 points);

Fundable (70–80 points); or

Unfundable (0–69 points).

For decision-making purposes, applications receiving the same adjectival rating will be considered to have an equivalent ranking, although their technical review scores, while comparable, may not necessarily be the same.

The Selecting Official is the NIST Associate Director for Innovation and Industry Services or designee. The Selecting Official makes the final recommendation to the NIST Grants Officer regarding the funding of applications under this notice and the corresponding FFO. The Selecting Official shall be provided all applications, all the scores and technical assessments of the reviewers, and all information obtained from the applicants during the evaluation, review and negotiation processes.

The Selecting Official will generally select and recommend the most meritorious application for an award based on the adjectival rankings and/or one or more of the six (6) selection factors described in the Selection Factors section of this notice and Section V.3. of the corresponding FFO. The Selecting Official retains the discretion to select and recommend an application out of rank order (*i.e.,* from a lower adjectival category) based on one or more of the selection factors, or to select and recommend no applications for funding. The Selecting Official's recommendation to the Grants Officer shall set forth the bases for the selection decision.

As part of the overall review and selection process, NIST reserves the right to request that applicants provide pre-award clarifications and/or to enter into pre-award negotiations with applicants relative to programmatic, financial or other aspects of an application, such as but not limited to the revision or removal of proposed budget costs, or the modification of proposed MEP Center activities, work plans or program goals and objectives. In this regard, NIST may request that applicants provide supplemental information required by the Agency prior to award. NIST also reserves the right to reject an application where information is uncovered that raises a reasonable doubt as to the responsibility of the applicant. The final approval of selected applications and issuance of awards will be by the NIST Grants Officer. The award decisions of the NIST Grants Officer are final.

Federal Awarding Agency Review of Risk Posed by Applicants. After applications are proposed for funding by the Selecting Official, the NIST Grants Management Division (GMD) performs pre-award risk assessments in accordance with 2 CFR 200.205, which may include a review of the financial stability of an applicant, the quality of the applicant's management systems, the history of performance, and/or the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. In addition, prior to making an award where the total Federal share is expected to exceed the simplified acquisition threshold (currently $150,000), NIST GMD will review and consider the publicly available information about that applicant in the Federal Awardee Performance and Integrity Information System (FAPIIS). An applicant may, at its option, review and comment on information about itself previously entered into FAPIIS by a Federal awarding agency. As part of its review of risk posed by applicants, NIST GMD will consider any comments made by the applicant in FAPIIS in making its determination about the applicant's integrity, business ethics, and record of performance under Federal awards. Upon completion of the pre-award risk assessment, the Grants Officer will make a responsibility determination concerning whether the applicant is qualified to receive the subject award and, if so, whether appropriate special conditions that correspond to the degree of risk posed by the applicant should be applied to an award.

Anticipated Announcement and Award Date. Review, selection, and award processing is expected to be completed in early 2017. The anticipated start date for awards made under this notice and the corresponding FFO is expected to be April 1, 2017.

Additional Information

a. Application Replacement Pages. Applicants may not submit replacement pages and/or missing documents once an application has been submitted. Any revisions must be made by submission of a new application that must be received by NIST by the submission deadline.

b. Notification to Unsuccessful Applicants. Unsuccessful applicants will be notified in writing.

c. Retention of Unsuccessful Applications. An electronic copy of each non-selected application will be retained for three (3) years for record keeping purposes. After three (3) years, it will be destroyed.

Administrative and National Policy Requirements

Uniform Administrative Requirements, Cost Principles and Audit Requirements: Through 2. CFR 1327.101, the Department of Commerce adopted the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 CFR part 200, which apply to awards made pursuant to this notice and the corresponding FFO. Refer to *http://go.usa.gov/SBYh* and *http://go.usa.gov/SBg4.*

The Department of Commerce Pre-Award Notification Requirements: The Department of Commerce will apply the Pre-Award Notification Requirements for Grants and Cooperative Agreements dated December 30, 2014 (79 FR 78390). If the Department of Commerce publishes revised Pre-Award Notification Requirements prior to issuance of awards under this notice and the corresponding FFO, the revised Pre-Award Notification Requirements will apply. Refer to Section VII. of the corresponding FFO, Federal Awarding Agency Contacts, Grant Rules and Regulations for more information.

Unique Entity Identifier and System for Award Management (SAM): Pursuant to 2 CFR part 25, applicants and recipients (as the case may be) are required to: (i) Be registered in SAM before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency, unless otherwise excepted from these requirements pursuant to 2 CFR 25.110. NIST will not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and

SAM requirements. If an applicant has not fully complied with the requirements by the time that NIST is ready to make a Federal award pursuant to this notice and the corresponding FFO, NIST may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

Paperwork Reduction Act: The standard forms in the application kit involve a collection of information subject to the Paperwork Reduction Act. The use of Standard Forms 424, 424A, 424B, and SF–LLL have been approved by OMB under the respective Control Numbers 4040–0004, 4040–0006, 4040–0007, and 0348–0046.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

Certifications Regarding Federal Felony and Federal Criminal Tax Convictions, Unpaid Federal Tax Assessments and Delinquent Federal Tax Returns. In accordance with Federal appropriations law, an authorized representative of the selected applicant(s) may be required to provide certain pre-award certifications regarding Federal felony and Federal criminal tax convictions, unpaid Federal tax assessments, and delinquent Federal tax returns.

Funding Availability and Limitation of Liability: Funding for the program listed in this notice and the corresponding FFO is contingent upon the availability of appropriations. In no event will NIST or DoC be responsible for application preparation costs if this program fails to receive funding or is cancelled because of agency priorities. Publication of this notice and the corresponding FFO does not oblige NIST or DoC to award any specific project or to obligate any available funds.

Other Administrative and National Policy Requirements: Additional administrative and national policy requirements are set forth in Section VI.2. of the corresponding FFO.

Executive Order 13132 (Federalism): It has been determined that this notice does not contain policies with federalism implications as that term is defined in Executive Order 13132.

Executive Order 12372: Proposals under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Administrative Procedure Act/Regulatory Flexibility Act: Notice and comment are not required under the Administrative Procedure Act (5 U.S.C. 553) or any other law, for matters relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553(a)). Moreover, because notice and comment are not required under 5 U.S.C. 553, or any other law, for matters relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553(a)), a Regulatory Flexibility Analysis is not required and has not been prepared for this notice, 5 U.S.C. 601 *et seq.*

Phillip Singerman,

Associate Director for Innovations and Industry Services.

[FR Doc. 2016–15539 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Judges Panel of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of closed meeting.

SUMMARY: The Judges Panel of the Malcolm Baldrige National Quality Award (Judges Panel) will meet in closed session on Wednesday, August 17, 2016, from 9 a.m. to 3:30 p.m. Eastern time. The purpose of this meeting is to review the results of examiners' scoring of written applications. Panel members will vote on which applicants merit site visits by examiners to verify the accuracy of quality improvements claimed by applicants. The meeting is closed to the public in order to protect the proprietary data to be examined and discussed at the meeting.

DATES: The meeting will be held on Wednesday, August 17, 2016, from 9 a.m. to 3:30 p.m. Eastern time. The entire meeting will be closed to the public.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, Maryland 20899–1020, telephone number (301) 975–2360, email *robert.fangmeyer@nist.gov.*

SUPPLEMENTARY INFORMATION:

Authority: 15 U.S.C. 3711a(d)(1) and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Judges Panel of the Malcolm Baldrige National Quality Award will meet on Wednesday, August 17, 2016, from 9 a.m. to 3:30 p.m. Eastern time. The Judges Panel is composed of twelve members, appointed by the Secretary of Commerce, with a balanced representation from U.S. service, manufacturing, nonprofit, education, and health care industries. Members are selected for their familiarity with quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, health care providers, and educational institutions. Members are also chosen who have broad experience in for-profit and nonprofit areas. The purpose of this meeting is to review the results of examiners' scoring of written applications. Panel members will vote on which applicants merit site visits by examiners to verify the accuracy of quality improvements claimed by applicants. The meeting is closed to the public in order to protect the proprietary data to be examined and discussed.

The Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the Acting, Assistant General Counsel for Administration, formally determined on May 19, 2016, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in Sunshine Act, Public Law 94–409, that the meeting of the Judges Panel may be closed to the public in accordance with 5 U.S.C. 552b(c)(4) because the meeting is likely to disclose trade secrets and commercial or financial information obtained from a person which is privileged or confidential and 5 U.S.C. 552b(c)(9)(B) because for a government agency the meeting is likely to disclose information that could significantly frustrate implementation of a proposed agency action. The meeting, which involves examination of current Malcolm Baldrige National Quality Award (Award) applicant data from U.S. organizations and a discussion of these data as compared to the Award criteria in order to recommend Award recipients, will be closed to the public.

Kevin Kimball,

NIST Chief of Staff.

[FR Doc. 2016–15488 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Sea Grant Advisory Board (NSGAB)

AGENCY: National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the NSGAB. NSGAB members will discuss and provide advice on the National Sea Grant College Program (NSGCP) in the areas of program evaluation, strategic planning, education and extension, science and technology programs, and other matters as described in the agenda found on the NSGCP Web site at *http://seagrant.noaa.gov/WhoWeAre/Leadership/NationalSeaGrantAdvisoryBoard/UpcomingAdvisoryBoardMeetings.aspx.*

DATES: The announced meeting is scheduled for Friday, August 12, 2016 from 3:00–5:00 p.m. EDT.

ADDRESSES: The meeting will be held via conference call. Public access is also available at 1315 East-West Highway, Bldg. 3, Room #11817, Silver Spring, MD 20910. In order to attend in person or via conference call, please R.S.V.P to Jennifer Hinden (contact information below) by Friday, July 29, 2016.

STATUS: The meeting will be open to public participation with a 10-minute public comment period from 4:50–5:00 p.m. EDT. Please check the agenda using link in the Summary section to confirm time.

The NSGAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by Mrs. Jennifer Hinden by Friday, July 22nd, 2016 to provide sufficient time for NSGAB review. Written comments received after the deadline will be distributed to the NSGAB, but may not be reviewed prior to the meeting date. Seats will be available on a first-come, first-serve basis.

Contact Information: For any questions concerning the meeting or to R.S.V.P., please contact Mrs. Jennifer Hinden, National Sea Grant College Program, National Oceanic and Atmospheric Administration, 1315 East-West Highway, Room 11717, Silver Spring, Maryland 20910, 301–734–1083, *Jennifer.Hinden@noaa.gov.*

Special Accomodations: These meetings are physically accessible to people with disabilities. If you would like to attend in person, requests for sign language interpretation or other auxiliary aids should be directed to Mrs. Jennifer Hinden by Friday, July 22nd, 2016.

SUPPLEMENTARY INFORMATION: The NSGAB, which consists of a balanced representation from academia, industry, state government and citizens groups, was established in 1976 by Section 209 of the Sea Grant Improvement Act (Pub. L. 94–461, 33 U.S.C. 1128).

The NSGAB advises the Secretary of Commerce and the Director of the NSGCP with respect to operations under the Act, and such other matters as the Secretary refers to them for review and advice.

Dated: June 24, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–15595 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–KA–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Greater Atlantic Region Permit Family of Forms.

OMB Control Number: 0648–0202.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 135, 938.

Average Hours per Response:

Vessel Permits

Vessel permit application: 45 minutes; vessel permit renewal forms: 30 minutes; initial dealer permit applications: 15 minutes; dealer permit renewal forms: 5 minutes; initial and renewal vessel operator permit applications: 1 hour; obtaining and submitting a dealer or vessel owner email address: 5 minutes; limited access vessel replacement applications: 1.5 hours; and applications for retention of limited access permit history: 1.5 hours.

VMS Requirements

Installing a VMS unit: 1 hour; confirming VMS connectivity: 5 minutes; VMS certification form: 5 minutes; VMS installation for Canadian herring transport vessels: 1 hour and 20 minutes; email to declare their entrance and departure from U.S. waters: 15 minutes; automatic polling of vessel position using the VMS unit: 0 minutes; area and DAS declarations: 5 minutes; declaration of days-out of the gillnet fishery for monkfish and NE multispecies vessels: 5 minutes; Good Samaritan DAS credit request: 30 minutes; entangled whale DAS credit request: 30 minutes; DAS credit for a canceled trip due to unforeseen circumstances, but have not yet begun fishing: 5 minutes to request via the VMS unit and 10 minutes to request via the paper form; VMS catch reports: 5 minutes; VMS power down exemption: 30 minutes.

Observer Program Call-In Requirements

Requests for observer coverage are estimated to require either 2 or 10 minutes per request, depending on the program for which observers are requested.

Exempted Fisheries Programs

Letter of Authorization (LOA) to participate in any of the exemption programs: 5 minutes; Charter/Party Exemption Certificate for GOM Closed Areas: 5 minutes; limited access sea scallop vessels state waters DAS exemption program or state waters gear exemption program: 2 minutes; withdraw from either state waters exemption program prior to the end of the 7-day designated exemption period requirement: 2 minutes; request for change in permit category designation: 5 minutes; request for transit to another port by a vessel required to remain within the GOM cod trip limit: 2 minutes; gillnet category designation, including initial requests for gillnet tags: 10 minutes; requests for additional tags: 2 minutes; notification of lost tags and requests for replacement tag numbers: 2

minutes; attachment of gillnet tags: 1 minute; initial lobster area designations: 5 minutes; requests for additional tags: 2 minutes; and notification of lost tags: 3 minutes; requests for state quota transfers in the bluefish, summer flounder and scup fisheries: 1 hour; GOM cod trip limit exemption: 5 minutes; vessel owner single letter option: 5 minutes.

Burden Hours: 18,125.

Needs and Uses: This request is for extension of a current information collection.

Under the Magnuson-Stevens Fishery Conservation and Management Act, the Secretary of Commerce has the responsibility for the conservation and management of marine fishery resources. Much of this responsibility has been delegated to NOAA's National Marine Fisheries Service (NMFS). Under this stewardship role, the Secretary was given certain regulatory authorities to ensure the most beneficial uses of these resources. One of the regulatory steps taken to carry out the conservation and management objectives is to collect information from users of the resources.

The Secretary has enacted rules to issue permits to individuals and organizations participating in federally controlled fisheries. Permits are necessary to: (1) Register fishermen, fishing vessels, fish dealers and processors; (2) list the characteristics of fishing vessels and/or dealer/processor operations; (3) exercise influence over compliance (*e.g.*, withhold issuance pending collection of unpaid penalties); (4) maintain contact lists for the dissemination of important information to the industry; (5) register participants to be considered for limited entry; and (6) provide a universe for data collection samples. Identification of fishery participants, their gear types, vessels, and expected activity levels is an effective and necessary tool in the enforcement of fishery regulations.

This collection also includes the requirement for participants in certain fisheries to use onboard vessel monitoring systems (VMS) and to notify NMFS before fishing trips for the purpose of observer placement. Other permitting in this collection includes the written request to participate in any of the various exemption programs offered in the Greater Atlantic region. Exemption programs may allow a vessel to fish in an area that is limited to vessels of a particular size, using a certain gear type, or fishing for a particular species. This collection also contains paperwork required for vessel owners to request gillnet and lobster trap tags through the Greater Atlantic region permit office.

Lastly, vessel owners that own multiple vessels, but would like to request communication from NMFS be consolidated into one mailing (and not separate mailings for each vessel), may request the single letter vessel owner option to improve efficiency of their business practice.

Affected Public: Business or other for-profit organizations; individuals or households; state, local or tribal governments.

Frequency: On occasion, weekly, monthly, annual and every three years.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: June 27, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–15522 Filed 6–29–16; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection 3038–0102, Clearing Exemption for Certain Swaps Entered Into by Cooperatives

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is announcing an opportunity for public comment on the proposed collection renewal of certain information by the agency. Under the Paperwork Reduction Act ("PRA"), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. This notice solicits comments on the reporting requirements related to Commission regulation 50.51, which permits certain cooperatives to elect not to clear certain swaps that otherwise would be required to be cleared, provided that they meet certain conditions.

DATES: Comments must be submitted on or before August 29, 2016.

ADDRESSES: You may submit comments, identified by "Clearing Exemption for Certain Swaps Entered into by Cooperatives," or OMB Control No. 3038–0102, by any of the following methods:

- The Commission's Web site, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.
- *Federal eRulemaking Portal: http://www.regulations.gov/.* Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa A. D'Arcy, Special Counsel, Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581; (202) 418–5086; email: *mdarcy@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget ("OMB") for each collection of information they conduct or sponsor. "Collection of Information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

Title: Clearing Exemption for Certain Swaps Entered into by Cooperatives (OMB Control No. 3038–0102). This is a request for an extension of a currently approved information collection.

Abstract: Section 2(h)(1)(A) of the Commodity Exchange Act requires certain entities to submit for clearing certain swaps if they are required to be cleared by the Commission. Commission regulation 50.51 permits certain cooperatives to elect not to clear certain swaps that otherwise would be required to be cleared, provided that they meet certain conditions. The rule further requires the reporting of certain information if the exemption for cooperatives is elected. This collection pertains to information the Commission needs to monitor use of the exemption and assess market risk in connection therewith.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The Commission is revising its estimate of the burden for this collection to update the estimated number of respondents and the estimated burden hours. The respondent burden for this collection is estimated to be as follows:

Respondents/Affected Entities: Parties electing the cooperative exemption under Commission regulation 50.51.

Estimated number of respondents: 25.

Estimated average burden hours per Respondent: 1 hour.

Estimated total annual burden hours on respondents: 25 hours.

Frequency of collection: Annually; on occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 24, 2016.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2016–15473 Filed 6–29–16; 8:45 am]

BILLING CODE 6351–01–P

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[1] 17 CFR 145.9.

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection 3038–0005, Rules Relating to the Operations and Activities of Commodity Pool Operators and Commodity Trading Advisors and to Monthly Reporting by Futures Commission Merchants

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act ("PRA"), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on requirements relating to reporting and recordkeeping by Commodity Pool Operators and Commodity Trading Advisors.

DATES: Comments must be submitted on or before August 29, 2016.

ADDRESSES: You may submit comments, identified by "Renewal of Collection Relating to the Operations and Activities of Commodity Pool Operators and Commodity Trading Advisors and to Monthly Reporting by Futures Commission Merchants" by any of the following methods:

- The Agency's Web site, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.
- *Federal eRulemaking Portal: http://www.regulations.gov/.* Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

FOR FURTHER INFORMATION CONTACT: Amanda Olear, Associate Director, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, 1155 21st St. NW., Washington, DC 20581, (202) 418–5283; email: *aolear@cftc.gov,* and refer to OMB Control No. 3038–0005.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget ("OMB") for each collection of information they conduct or sponsor. "Collection of Information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

Title: Rules Relating to the Operations and Activities of Commodity Pool Operators and Commodity Trading Advisors and to Monthly Reporting by Futures Commission Merchants (OMB Control No. 3038–0005). This is a request for extension of a currently approved information collection.

Abstract: Pursuant to the Commodity Exchange Act, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"), Public Law 111–203, 124 Stat. 1376 (2010), the Commission promulgated rules and forms relating to registration and compliance with the Commission regulations applicable to intermediaries, and employees and principals thereof, operating in the futures, options, swaps, and retail forex markets. As part of the Commission's rulemaking effort, the

Commission amended the compliance regime for Commodity Pool Operators, which is part of a previously approved information collection, through the adoption of a compliance regime applicable to Commodity Pool Operators of Registered Investment Companies, 78 FR 52308 (Aug. 22, 2013).

The disclosure, filing, and recordkeeping requirements within part 4 of the Commission's regulations were established to assist customers, to facilitate the Commission and the National Futures Association ("NFA") in monitoring compliance with the part 4 rules, and to enable the Commission to better monitor the market risks posed by the Commission's registrants. The information collections are necessary to enable the Commission and NFA to accomplish the purposes of the compliance regime set forth in part 4 enumerated above.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov*. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The respondent burden for this collection is estimated to be 4 hours[2] per response.

Respondents/Affected Entities: Commodity Pool Operators, Commodity Trading Advisors.

Estimated Number of Respondents: 48,046.

Estimated Total Annual Burden Hours on Respondents: 276,060 hours.[3]

Frequency of Collection: Periodically.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 24, 2016.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2016–15472 Filed 6–29–16; 8:45 am]

BILLING CODE 6351–01–P

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[1] 17 CFR 145.9.

[2] This has been rounded down from 4.0348.

[3] The estimated total burden hours for the collections have been rounded down slightly, based on the estimated burden hour per response of 4.0348.

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2009–0088]

Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Conformity Assessment Body Registration Form

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Consumer Product Safety Commission ("CPSC" or "Commission") requests comments on a proposed extension of approval of a collection of information under the requirements pertaining to a third party conformity assessment body registration form, approved previously under OMB Control No. 3041–0143. The Commission will consider all comments received in response to this notice before requesting an extension of this collection of information from the Office of Management and Budget ("OMB").

DATES: Submit written or electronic comments on the collection of information by August 29, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2009–0088, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov*. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov*. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov*. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov*, and insert the docket number CPSC–2009–0088, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7815, or by email to: *rsquibb@cpsc.gov*.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Third Party Conformity Assessment Body Registration Form.

OMB Number: 3041–0143.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Third party conformity assessment bodies seeking acceptance of accreditation or continuing accreditation.

General Description of Collection

The Consumer Product Safety Improvement Act of 2008 ("CPSIA") requires third party testing be conducted by a third party conformity assessment body for any children's product, that is subject to a children's product safety rule, before importing for consumption or warehousing or distributing in commerce. The CPSIA allows accreditation of third party conformity assessment bodies to be conducted either by the Commission or by an independent accreditation organization designated by the Commission, and requires that the Commission maintain on its Web site an up-to-date list of entities that have been accredited to assess conformity with children's product safety rules. With the exception of firewalled third party conformity assessment bodies, the Commission has chosen to accept the accreditation of third party conformity assessment bodies that meet accreditation requirements of an independent accreditation organization.

In order to assess a third party conformity assessment body's qualifications for acceptance by CPSC, information related to location, accreditation, and ownership must be collected from third party conformity assessment bodies. The CPSC uses an online collection form, CPSC Form 223, to gather information from third party conformity assessment bodies voluntarily seeking acceptance by CPSC. The information collected relates to location, accreditation, and ownership. The Commission staff uses this information to assess:

- A third party conformity assessment body's status as either an independent third party conformity assessment body, a government-owned or government-controlled conformity assessment body, or a firewalled conformity assessment body;
- Qualifications for acceptance by CPSC to test for compliance to specified children's product safety rules; and
- Eligibility for acceptance on the CPSC Web site.

Part 1112 requires the collection of information in CPSC Form 223:

- Upon initial application by the third party conformity assessment body for acceptance by CPSC;
- Whenever there is a change to accreditation or ownership information; and
- At least every 2 years as part of a regular audit process.

Burden Estimates

The CPSC estimates the burden of the collection of information in CPSC Form 223 is as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total hours
Initial Registration	40	1	40	1	40
Re-Registration	243	1	243	1	243
Changes in Information	2	1	2	0.25	0.5
Total					283.5

These estimates are based on the following information:

- From March 23, 2015 to March 23, 2016, 39 new third party conformity assessment bodies have registered with the CPSC; 36 registered during the previous 12 months. Therefore, we estimate the number of third party conformity assessment bodies who would register initially each year for the next three years would be 40.
- Under 16 CFR part 1112, third party conformity assessment bodies are required to resubmit CPSC Form 223 every two years. Because all third party conformity assessment bodies have not submitted their first CPSC Form 223s at the same time, only about half would be expected to resubmit a CPSC Form 223 in any one year. As of March 2016, 487 third party conformity assessment bodies have registered with CPSC. Approximately half (243) of these firms would be required to re-register with CPSC each year.
- Under 16 CFR part 1112, third party conformity assessment bodies are required to ensure that the information submitted on CPSC Form 223 is current and must submit a new CPSC Form 223 whenever the information changes. Based on current experience with third party conformity assessment bodies, we estimate that two third party conformity assessment bodies will make revisions per year to update their information. A change in information is a change that does not require review of laboratory accreditation documents, such as scope or test methods. Examples of revised information include changes in the Web site URL, name of the laboratory, and name of point of contact.

The total burden, therefore, is 283.5 hours, which we will round up to 284 hours. We estimate that hourly compensation for the time required for recordkeeping is $32.82 per hour (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," Table 9, total compensation for sales, office, and related workers in goods-producing industries, December 2015: *http://www.bls.gov/ncs*). The total cost burden to the respondents is approximately $9,321 ($32.82 × 284 hours = $9,321.88).

Request for Comments

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- Whether the estimated burden of the proposed collection of information is accurate;
- Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- Whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Dated: June 27, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–15496 Filed 6–29–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–17]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

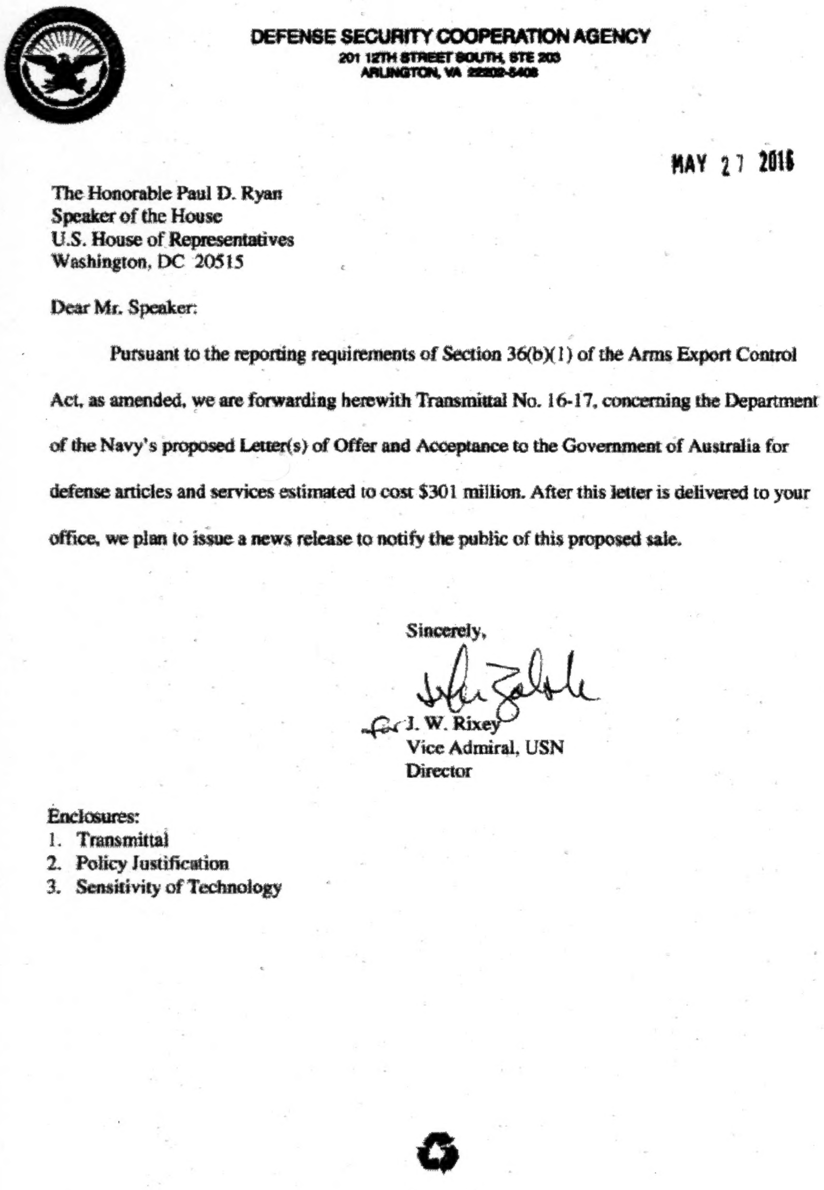
The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–17 with attached Policy Justification and Sensitivity of Technology.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 27 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-17, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Australia for defense articles and services estimated to cost $301 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

for J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 16–17

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Australia

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$216 million
Other	$ 85 million
Total	$301 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Up to eighty (80) STANDARD Missile, SM–2 Block IIIB Vertical Launching Tactical All-Up Rounds, RIM–66M–09

Up to fifteen (15) MK 97 SM–2 Block IIIB Guidance Sections (GSs)

Non-MDE:

This request also includes the following Non-MDE: MK 13 MOD 0 Vertical Launching System Canisters, operator manuals and technical documentation, U.S. Government and contractor engineering, technical and logistics support services.

(iv) *Military Department:* Navy (AMM)

(v) *Prior Related Cases, if any:* AT–P–AYR–28 JUL 10–$39,499,569, AT–P–LCY–30 APR 05–$221,521,728, AT–P–GSQ–22 APR 11–$58,842,285

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Annex attached

(viii) *Date Report Delivered to Congress:* 27 May 2016

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Australia—SM–2 Block IIIB STANDARD Missiles

The Government of Australia requested a possible sale of:

Major Defense Equipment (MDE):

Up to eighty (80) STANDARD Missile, SM–2 Block IIIB Vertical Launching Tactical All-Up Rounds, RIM–66M–09

Up to fifteen (15) MK 97 SM–2 Block IIIB Guidance Sections (GSs)

This request also includes the following Non-MDE: MK 13 MOD 0 Vertical Launching System Canisters, operator manuals and technical documentation, U.S. Government and contractor engineering, technical and logistics support services.

The total estimated value of MDE is $216 million. The total overall estimated value is $301 million.

Australia is one of the major political and economic powers in Southeast Asia, a key democratic partner of the United States in ensuring regional peace and stability, a close coalition ally in major/lesser regional contingency operations, and a close cooperative and international exchange agreement partner. It is vital to U.S. national interests that Australia develops and maintains a strong and ready self-defense capability. This sale is consistent with U.S. regional objectives.

The SM–2 Block IIIB missiles proposed in this purchase will be used for anti-air warfare test firings during Combat Systems Ship Qualification Trials for the Royal Australian Navy's three new Air Warfare Destroyers (AWD) currently under construction). The SM–2 Block IIIB missiles, combined with the Aegis combat systems in the AWDs, will provide significantly enhanced area defense capabilities over critical South East Asian air-and-sea-lines of communication. Australia has already integrated the SM–2 Block IIIA into its Perry-class FFGs and recently upgraded its Intermediate-Level Maintenance Depot at Defense Establishment Orchard Hills with new guided missile test equipment capable of maintaining the SM–2 All-Up Round. Australia will have no difficulty absorbing these new missiles.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be Raytheon Missile Systems Company, Tucson, Arizona; Raytheon Company, Camden, Arkansas; and BAE of Minneapolis and Aberdeen, South Dakota. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will not require the assignment of any U.S. or contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 16–17

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. A completely assembled STANDARD Missile-2 (SM–2) Block IIIB with or without a conventional warhead, whether a tactical, telemetry or inert (training) configuration, is classified CONFIDENTIAL. Missile component hardware includes: Guidance Section (classified CONFIDENTIAL), Target Detection Device (classified CONFIDENTIAL), Warhead (UNCLASSIFIED), Rocket Motor (UNCLASSIFIED), Steering Control Section (UNCLASSIFIED), Safe and Arming Device (UNCLASSIFIED), Autopilot Battery Unit (classified CONFIDENTIAL), and if telemetry missiles, AN/DKT–71 Telemeters (UNCLASSIFIED).

2. SM–2 operator and maintenance documentation is usually CONFIDENTIAL. Shipboard operation/firing guidance is generally CONFIDENTIAL. Pre-firing missile assembly/pedigree information is UNCLASSIFIED.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Australia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Australia.

[FR Doc. 2016–15517 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2015–OS–0065]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Spouse Education and Career Opportunities Program (SECO); OMB Control Number 0704–XXXX.

Type of Request: New.

Number of Respondents: 26,000.

Responses per Respondent: 1.

Annual Responses: 26,000.

Average Burden per Response: 45 minutes.

Annual Burden Hours: 19,500.

Needs and Uses: This information collection requirement is necessary to allow eligible military spouses to access education and employment resources.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–15543 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: Defense Travel Management Office, DoD.

ACTION: Notice of Revised Non-Foreign Overseas Per Diem Rates.

SUMMARY: The Defense Travel Management Office is publishing Civilian Personnel Per Diem Bulletin Number 304. This bulletin lists revisions in the per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States when applicable. AEA changes announced in Bulletin Number 194 remain in effect. Bulletin Number 304 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates.

DATES: *Effective Date:* July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Sonia Malik, 571–372–1276.

SUPPLEMENTARY INFORMATION: This document gives notice of revisions in per diem rates prescribed by the Defense Travel Management Office for non-foreign areas outside the contiguous United States. It supersedes Civilian Personnel Per Diem Bulletin Number 303. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of revisions in per diem rates to agencies and establishments outside the Department of Defense. For more information or questions about per diem rates, please contact your local travel office. Civilian Bulletin 304 includes updated rates for Alaska, Northern Mariana Islands, and Wake Island.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
ALASKA						
[OTHER]						
01/01 - 12/31	120		76		196	03/01/2016
ADAK						
10/01 - 04/30	150		51		201	03/01/2016
05/01 - 09/30	192		51		243	03/01/2016
ANCHORAGE [INCL NAV RES]						
05/16 - 09/30	339		114		453	03/01/2016
10/01 - 05/15	99		114		213	03/01/2016
BARROW						
01/01 - 12/31	205		96		301	03/01/2016
BARTER ISLAND LRRS						
01/01 - 12/31	120		76		196	03/01/2016
BETHEL						
01/01 - 12/31	179		121		300	03/01/2016
BETTLES						
01/01 - 12/31	175		79		254	03/01/2015
CAPE LISBURNE LRRS						
01/01 - 12/31	120		76		196	03/01/2016
CAPE NEWENHAM LRRS						
01/01 - 12/31	120		76		196	03/01/2016
CAPE ROMANZOF LRRS						
01/01 - 12/31	120		76		196	03/01/2016
CLEAR AB						
01/01 - 12/31	120		76		196	03/01/2016
COLD BAY LRRS						
01/01 - 12/31	120		76		196	03/01/2016
COLDFOOT						
01/01 - 12/31	165		70		235	10/01/2006
COPPER CENTER						
05/15 - 09/15	150		86		236	03/01/2016

LOCALITY	(A) +	(B) =	(C)	EFFECTIVE DATE
09/16 - 05/14	115	86	201	03/01/2016
CORDOVA				
01/01 - 12/31	140	94	234	03/01/2016
CRAIG				
04/01 - 09/30	151	74	225	03/01/2016
10/01 - 03/31	88	74	162	03/01/2016
DEADHORSE				
01/01 - 12/31	170	51	221	03/01/2016
DELTA JUNCTION				
05/01 - 09/30	169	60	229	03/01/2015
10/01 - 04/30	139	57	196	03/01/2015
DENALI NATIONAL PARK				
06/01 - 08/31	185	80	265	03/01/2016
09/01 - 05/31	139	80	219	03/01/2016
DILLINGHAM				
05/01 - 10/15	350	85	435	03/01/2016
10/16 - 04/30	220	85	305	03/01/2016
DUTCH HARBOR-UNALASKA				
01/01 - 12/31	142	77	219	03/01/2016
EARECKSON AIR STATION				
01/01 - 12/31	146	74	220	07/01/2016
EIELSON AFB				
05/15 - 09/15	154	78	232	03/01/2016
09/16 - 05/14	75	78	153	03/01/2016
ELFIN COVE				
01/01 - 12/31	275	51	326	03/01/2016
ELMENDORF AFB				
05/16 - 09/30	339	114	453	03/01/2016
10/01 - 05/15	99	114	213	03/01/2016
FAIRBANKS				
05/15 - 09/15	154	78	232	03/01/2016
09/16 - 05/14	75	78	153	03/01/2016
FOOTLOOSE				
01/01 - 12/31	175	18	193	10/01/2002

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
FORT YUKON LRRS						
01/01 - 12/31	120		76		196	03/01/2016
FT. GREELY						
10/01 - 04/30	139		57		196	03/01/2015
05/01 - 09/30	169		60		229	03/01/2015
FT. RICHARDSON						
05/16 - 09/30	339		114		453	03/01/2016
10/01 - 05/15	99		114		213	03/01/2016
FT. WAINWRIGHT						
05/15 - 09/15	154		78		232	03/01/2016
09/16 - 05/14	75		78		153	03/01/2016
GAMBELL						
01/01 - 12/31	133		51		184	03/01/2016
GLENNALLEN						
05/15 - 09/15	150		86		236	03/01/2016
09/16 - 05/14	115		86		201	03/01/2016
HAINES						
01/01 - 12/31	107		101		208	01/01/2011
HEALY						
09/01 - 05/31	139		80		219	03/01/2016
06/01 - 08/31	185		80		265	03/01/2016
HOMER						
05/01 - 09/30	194		90		284	03/01/2016
10/01 - 04/30	89		90		179	03/01/2016
JB ELMENDORF-RICHARDSON						
05/16 - 09/30	339		114		453	03/01/2016
10/01 - 05/15	99		114		213	03/01/2016
JUNEAU						
05/01 - 09/30	159		88		247	03/01/2016
10/01 - 04/30	125		88		213	03/01/2016
KAKTOVIK						
01/01 - 12/31	165		86		251	10/01/2002
KAVIK CAMP						
01/01 - 12/31	250		51		301	03/01/2016

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
KENAI-SOLDOTNA						
11/01 - 04/30	84		106		190	03/01/2016
05/01 - 10/31	179		106		285	03/01/2016
KENNICOTT						
01/01 - 12/31	285		85		370	03/01/2016
KETCHIKAN						
10/02 - 03/31	99		97		196	03/01/2016
04/01 - 10/01	250		97		347	03/01/2016
KING SALMON						
05/01 - 10/01	225		91		316	10/01/2002
10/02 - 04/30	125		81		206	10/01/2002
KING SALMON LRRS						
01/01 - 12/31	120		76		196	03/01/2016
KLAWOCK						
04/01 - 09/30	151		74		225	03/01/2016
10/01 - 03/31	88		74		162	03/01/2016
KODIAK						
05/01 - 09/30	157		81		238	03/01/2016
10/01 - 04/30	100		81		181	03/01/2016
KOTZEBUE						
01/01 - 12/31	219		137		356	06/01/2016
KULIS AGS						
10/01 - 05/15	99		114		213	03/01/2016
05/16 - 09/30	339		114		453	03/01/2016
MCCARTHY						
01/01 - 12/31	285		85		370	03/01/2016
MCGRATH						
01/01 - 12/31	160		65		225	03/01/2016
MURPHY DOME						
05/15 - 09/15	154		78		232	03/01/2016
09/16 - 05/14	75		78		153	03/01/2016
NOME						
05/01 - 09/30	200		116		316	06/01/2016
10/01 - 04/30	175		116		291	06/01/2016

LOCALITY	(A)	+ (B)	= (C)	EFFECTIVE DATE
NUIQSUT				
01/01 - 12/31	234	51	285	03/01/2016
OLIKTOK LRRS				
01/01 - 12/31	120	76	196	03/01/2016
PETERSBURG				
01/01 - 12/31	120	76	196	03/01/2016
POINT BARROW LRRS				
01/01 - 12/31	120	76	196	03/01/2016
POINT HOPE				
01/01 - 12/31	175	85	260	03/01/2016
POINT LAY				
01/01 - 12/31	255	51	306	03/01/2016
POINT LAY LRRS				
01/01 - 12/31	255	51	306	03/01/2016
POINT LONELY LRRS				
01/01 - 12/31	120	76	196	03/01/2016
PORT ALEXANDER				
02/01 - 08/31	210	51	261	03/01/2016
09/01 - 01/31	165	51	216	03/01/2016
PORT ALSWORTH				
01/01 - 12/31	135	88	223	10/01/2002
PRUDHOE BAY				
01/01 - 12/31	170	51	221	03/01/2016
SELDOVIA				
05/01 - 09/30	194	90	284	03/01/2016
10/01 - 04/30	89	90	179	03/01/2016
SEWARD				
10/01 - 04/30	99	84	183	03/01/2016
05/01 - 09/30	298	84	382	03/01/2016
SITKA-MT. EDGECUMBE				
01/01 - 12/31	200	98	298	03/01/2016
SKAGWAY				
04/01 - 10/01	250	97	347	03/01/2016
10/02 - 03/31	99	97	196	03/01/2016

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
SLANA						
05/01 - 09/30	139		55		194	02/01/2005
10/01 - 04/30	99		55		154	02/01/2005
SPARREVOHN LRRS						
01/01 - 12/31	120		76		196	03/01/2016
SPRUCE CAPE						
05/01 - 09/30	157		81		238	03/01/2016
10/01 - 04/30	100		81		181	03/01/2016
ST. GEORGE						
01/01 - 12/31	220		51		271	03/01/2016
TALKEETNA						
01/01 - 12/31	100		89		189	10/01/2002
TANANA						
05/01 - 09/30	200		116		316	06/01/2016
10/01 - 04/30	175		116		291	06/01/2016
TATALINA LRRS						
01/01 - 12/31	120		76		196	03/01/2016
TIN CITY LRRS						
01/01 - 12/31	120		76		196	03/01/2016
TOK						
05/15 - 09/30	95		83		178	03/01/2016
10/01 - 05/14	73		83		156	03/01/2016
UMIAT						
01/01 - 12/31	350		51		401	03/01/2016
VALDEZ						
05/16 - 09/16	169		89		258	03/01/2016
09/17 - 05/15	89		89		178	03/01/2016
WAINWRIGHT						
01/01 - 12/31	175		83		258	01/01/2011
WASILLA						
05/01 - 09/30	170		105		275	03/01/2016
10/01 - 04/30	99		105		204	03/01/2016
WRANGELL						
04/01 - 10/01	250		97		347	1478/01/20

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
10/02 - 03/31	99		97		196	03/01/2016
YAKUTAT						
01/01 - 12/31	105		94		199	01/01/2011
AMERICAN SAMOA						
AMERICAN SAMOA						
01/01 - 12/31	139		69		208	06/01/2015
PAGO PAGO						
01/01 - 12/31	139		69		208	12/01/2015
GUAM						
GUAM (INCL ALL MIL INSTAL)						
01/01 - 12/31	159		87		246	07/01/2015
JOINT REGION MARIANAS (ANDERSEN)						
01/01 - 12/31	159		87		246	07/01/2015
JOINT REGION MARIANAS (NAVAL BASE)						
01/01 - 12/31	159		87		246	07/01/2015
TAMUNING						
01/01 - 12/31	159		87		246	12/01/2015
HAWAII						
[OTHER]						
01/01 - 12/31	189		103		292	04/01/2016
CAMP H M SMITH						
01/01 - 12/31	177		123		300	04/01/2016
EASTPAC NAVAL COMP TELE AREA						
01/01 - 12/31	177		123		300	04/01/2016
FT. DERUSSEY						
01/01 - 12/31	177		123		300	04/01/2016
FT. SHAFTER						
01/01 - 12/31	177		123		300	04/01/2016
HICKAM AFB						
01/01 - 12/31	177		123		300	04/01/2016
HILO						
01/01 - 12/31	189		103		292	04/01/2016
HONOLULU						
01/01 - 12/31	177		123		300	1479/01/20

LOCALITY	(A) +	(B) =	(C)	EFFECTIVE DATE
ISLE OF HAWAII: HILO				
01/01 - 12/31	189	103	292	04/01/2016
ISLE OF HAWAII: OTHER				
01/01 - 12/31	189	148	337	04/01/2016
ISLE OF KAUAI				
01/01 - 12/31	325	135	460	04/01/2016
ISLE OF MAUI				
01/01 - 12/31	259	134	393	04/01/2016
ISLE OF OAHU				
01/01 - 12/31	177	123	300	04/01/2016
JB PEARL HARBOR-HICKAM				
01/01 - 12/31	177	123	300	04/01/2016
KAPOLEI				
01/01 - 12/31	177	123	300	04/01/2016
KEKAHA PACIFIC MISSILE RANGE FAC				
01/01 - 12/31	325	135	460	04/01/2016
KILAUEA MILITARY CAMP				
01/01 - 12/31	189	103	292	04/01/2016
LANAI				
01/01 - 12/31	254	118	372	04/01/2016
LIHUE				
01/01 - 12/31	325	135	460	04/01/2016
LUALUALEI NAVAL MAGAZINE				
01/01 - 12/31	177	123	300	04/01/2016
MCB HAWAII				
01/01 - 12/31	177	123	300	04/01/2016
MOLOKAI				
01/01 - 12/31	157	96	253	04/01/2016
NAS BARBERS POINT				
01/01 - 12/31	177	123	300	04/01/2016
PEARL HARBOR				
01/01 - 12/31	177	123	300	04/01/2016
PMRF BARKING SANDS				
01/01 - 12/31	325	135	460	04/01/2016

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
SCHOFIELD BARRACKS						
01/01 - 12/31	177		123		300	04/01/2016
TRIPLER ARMY MEDICAL CENTER						
01/01 - 12/31	177		123		300	04/01/2016
WHEELER ARMY AIRFIELD						
01/01 - 12/31	177		123		300	04/01/2016
MIDWAY ISLANDS						
MIDWAY ISLANDS						
01/01 - 12/31	125		77		202	04/01/2016
NORTHERN MARIANA ISLANDS						
[OTHER]						
01/01 - 12/31	60		95		155	07/01/2016
ROTA						
01/01 - 12/31	130		107		237	07/01/2015
SAIPAN						
01/01 - 12/31	140		98		238	07/01/2015
TINIAN						
01/01 - 12/31	60		95		155	07/01/2016
PUERTO RICO						
[OTHER]						
01/01 - 12/31	109		112		221	06/01/2012
AGUADILLA						
01/01 - 12/31	171		84		255	11/01/2015
BAYAMON						
06/01 - 11/30	167		88		255	12/01/2015
12/01 - 05/31	195		88		283	12/01/2015
CAROLINA						
06/01 - 11/30	167		88		255	12/01/2015
12/01 - 05/31	195		88		283	12/01/2015
CEIBA						
01/01 - 12/31	139		92		231	10/01/2012
CULEBRA						
01/01 - 12/31	150		98		248	03/01/2012
FAJARDO [INCL ROOSEVELT RDS NAVSTAT]						

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
01/01 - 12/31	139		92		231	10/01/2012
FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO]						
06/01 - 11/30	167		88		255	12/01/2015
12/01 - 05/31	195		88		283	12/01/2015
HUMACAO						
01/01 - 12/31	139		92		231	10/01/2012
LUIS MUNOZ MARIN IAP AGS						
06/01 - 11/30	167		88		255	12/01/2015
12/01 - 05/31	195		88		283	12/01/2015
LUQUILLO						
01/01 - 12/31	139		92		231	10/01/2012
MAYAGUEZ						
01/01 - 12/31	109		112		221	09/01/2010
PONCE						
01/01 - 12/31	149		89		238	09/01/2012
RIO GRANDE						
01/01 - 12/31	169		123		292	06/01/2012
SABANA SECA [INCL ALL MILITARY]						
06/01 - 11/30	167		88		255	12/01/2015
12/01 - 05/31	195		88		283	12/01/2015
SAN JUAN & NAV RES STA						
12/01 - 05/31	195		88		283	12/01/2015
06/01 - 11/30	167		88		255	12/01/2015
VIEQUES						
01/01 - 12/31	175		95		270	03/01/2012
VIRGIN ISLANDS (U.S.)						
ST. CROIX						
04/15 - 12/14	247		110		357	06/01/2015
12/15 - 04/14	299		116		415	06/01/2015
ST. JOHN						
05/01 - 12/03	170		107		277	08/01/2015
12/04 - 04/30	230		113		343	08/01/2015
ST. THOMAS						
01/01 - 12/31	240		112		352	08/01/2015

LOCALITY	(A)	+	(B)	=	(C)	EFFECTIVE DATE
WAKE ISLAND						
WAKE ISLAND						
01/01 - 12/31	129		70		199	07/01/2016

[FR Doc. 2016–15575 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–16]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

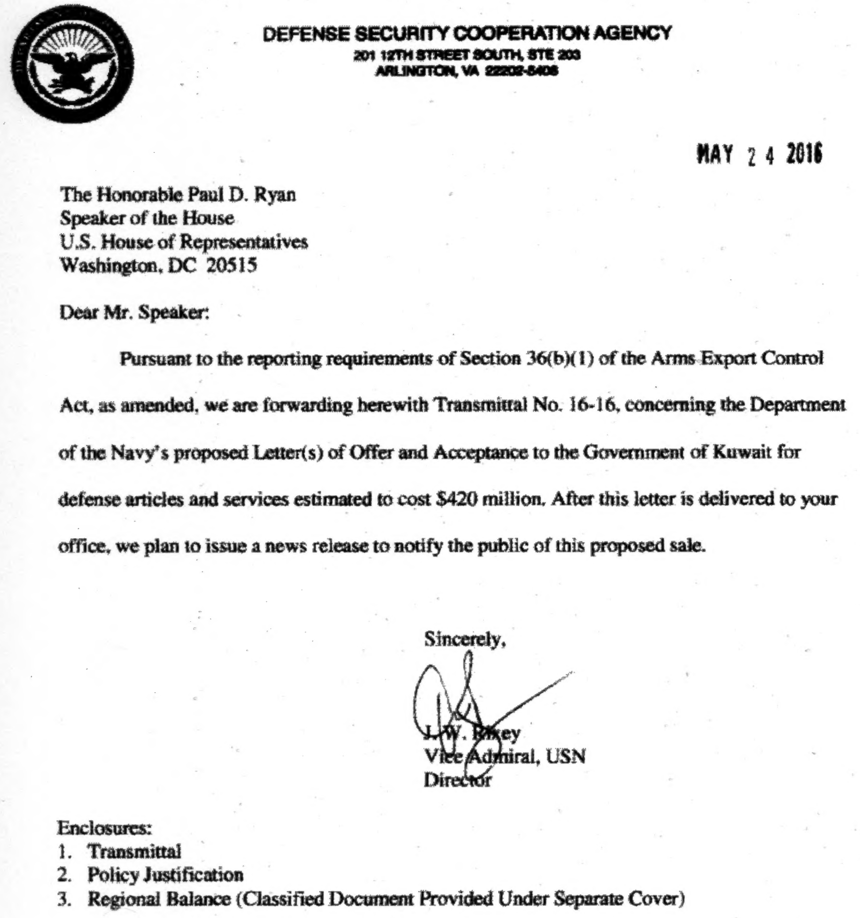
FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–16 with attached Policy Justification.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 24 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-16, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Kuwait for defense articles and services estimated to cost $420 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 16–16

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, As Amended

(i) *Prospective Purchaser:* Government of Kuwait

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$ 0 million
Other	$420 million
Total	$420 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Non-Major Defense Equipment (MDE):

This request includes the following Non-MDE: Continuation of contractor engineering technical services, contractor maintenance services, Hush House (an enclosed, noise-suppressed aircraft jet engine testing facility) support services, and Liaison Office Support for the Government of Kuwait F/A–18 C/D program. This will include F/A–18 avionics software upgrades, engine component improvements, ground support equipment, engine and aircraft spares and repair parts, publications and technical documentation, Engineering Change Proposals (ECP), U.S. Government and contractor programmatic, financial, and logistics support. Also included are: Maintenance and engineering support, F404 engine and engine test cell support, and Liaison Office support for five (5) Kuwait Liaison Offices. There is no MDE associated with this possible sale. The total overall estimated cost is $420 million.

(iv) *Military Department:* U.S. Navy (GHI, GHJ)

(v) *Prior Related Cases, if any:* FMS Cases: GGZ–$134,425,825–16 JUN 14 GGW–$177,181,190–25 DEC 13

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 24 May 2016

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

The Government of Kuwait—F/A–18 C/D Services and Support

The Government of Kuwait has requested a possible sale of the following Non-Major Defense Equipment (MDE): Continuation of contractor engineering technical services, contractor maintenance services, Hush House support services, and Liaison Office Support for the Government of Kuwait F/A–18 C/D program. This will include F/A–18 avionics software upgrades, engine component improvements, ground support equipment, engine and aircraft spares and repair parts, publications and technical documentation, Engineering Change Proposals (ECP), U.S. Government and contractor programmatic, financial, and logistics support. Also included are: Maintenance and engineering support, F404 engine and engine test cell support, and Liaison Office support for five (5) Kuwait Liaison Offices. There is no MDE associated with this possible sale. The total overall estimated value is $420 million.

The proposed sale of support services will enable the Kuwait Air Force to ensure the reliability and performance of its F/A–18 C/D aircraft. Kuwait will have no difficulty absorbing this support into its armed forces.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been, and continues to be, an important force for political stability and economic progress in the Middle East. Kuwait plays a large role in U.S. efforts to advance stability in the Middle East, providing basing, access, and transit for U.S. forces in the region.

The proposed sale of support and services will not alter the basic military balance in the region.

The principal contractors will be Kay and Associates Incorporated in Buffalo Grove, Illinois; The Boeing Company in St. Louis, Missouri; Industrial Acoustics Corporation in Winchester, England; General Electric in Lynn, Massachusetts; and Sigmatech in Huntsville, Alabama. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require two-hundred and seventy-five (275) contractor representatives to travel to Kuwait for a period of three (3) years to provide support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2016–15514 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–08]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

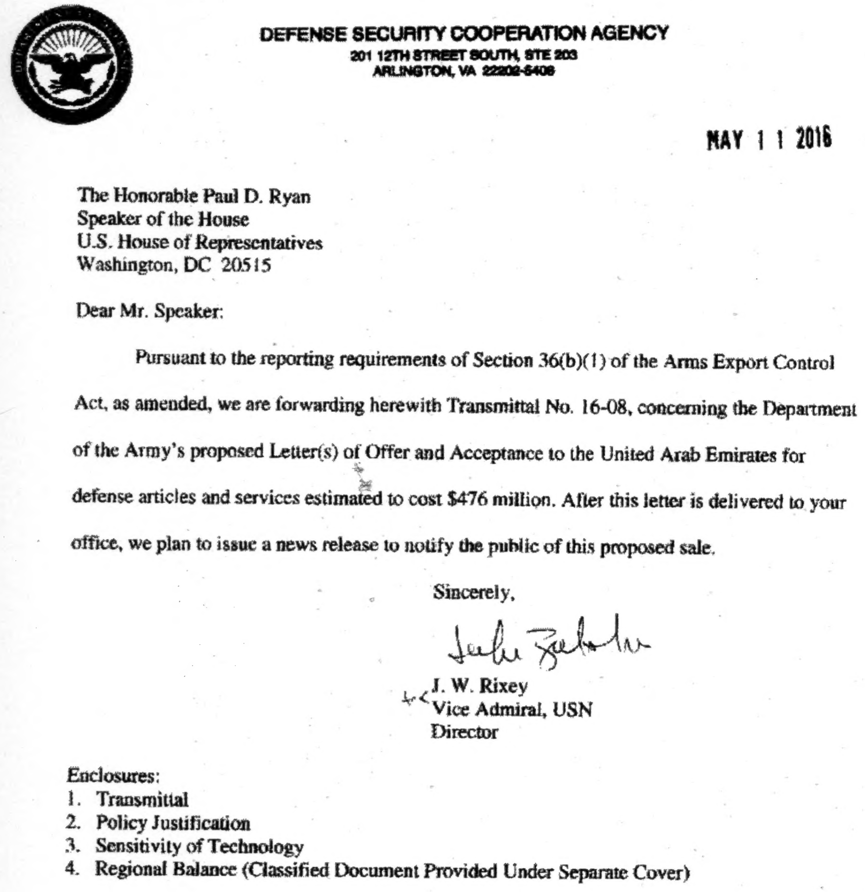
FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–08 with attached Policy Justification and Sensitivity of Technology.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 11 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-08, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to the United Arab Emirates for defense articles and services estimated to cost $476 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 16–08

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* United Arab Emirates

(ii) *Total Estimated Value:*

Major Defense Equipment *	$468 million
Other	8 million
Total	476 million.

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Four-thousand (4,000) AGM–114R/K Hellfire Missiles.

Also included are the following non-MDE items: Training and technical assistance. The estimated cost is $476 million.

(iv) *Military Department:* Army (AE–B–ZUF, Amendment 2).

(v) *Prior Related Cases, if any:* AE–B–JAH–02 Jan 92–$606 million, AE–B–UDE–06 Jan 00–$195 million, AE–B–ZUF–31 Dec 08–$174 million, AE–B–ZUL–21 Oct 09–$252 million.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* 11 May 2016.

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Arab Emirates—AGM–114 R/K Hellfire Category III Missiles

The United Arab Emirates (UAE) has requested a possible sale of four-thousand (4,000) AGM–114 R/K Hellfire Missiles over the next three (3) years in increments of one-thousand (1,000) to one-thousand five-hundred (1,500) missiles. Also included in this possible sale are training and technical assistance. The total estimated value of MDE is $468 million. The overall total estimated value is $476 million.

This proposed sale will enhance the foreign policy and national security of the United States by helping to improve the security of a partner country, which has been, and continues to be, an important force for political stability and economic progress in the Middle East.

The proposed sale will improve the UAE's capability to meet current and future threats and provide greater security for its critical infrastructure. The UAE will use the enhanced capability to strengthen its homeland defense. UAE will have no difficulty absorbing these Hellfire missiles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin Missile and Fire Control in Dallas, Texas. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any U.S. Government or contractor representatives to the United Arab Emirates.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 16–08

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

Annex—Item No. vii

(vii) Sensitivity of Technology

1. The AGM–114 R/K Hellfire Category III Missile is an air-to-ground missile used against heavy and light armored targets, thin-skinned vehicles, urban structures, bunkers, caves, and personnel. The missile is Inertial Measurement Unit-based, with a variable delay fuze, improved safety and reliability. The highest level for release of the AGM–114 R/K Hellfire Missile Semi-Active Laser is SECRET, based upon the software. The highest level of classified information that could be disclosed by a proposed sale or by testing of the end item is SECRET; the highest level that must be disclosed for production, maintenance or training is CONFIDENTIAL. Reverse engineering could reveal CONFIDENTIAL information. Vulnerability data, countermeasures, vulnerability/susceptibility analyses and threat definitions are classified up to SECRET.

2. A determination has been made that the Government of the United Arab Emirates can provide substantially the same degree of protection for the technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

3. All defense articles and services listed in this transmittal have been authorized for release and export to the United Arab Emirates.

[FR Doc. 2016–15516 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–20]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

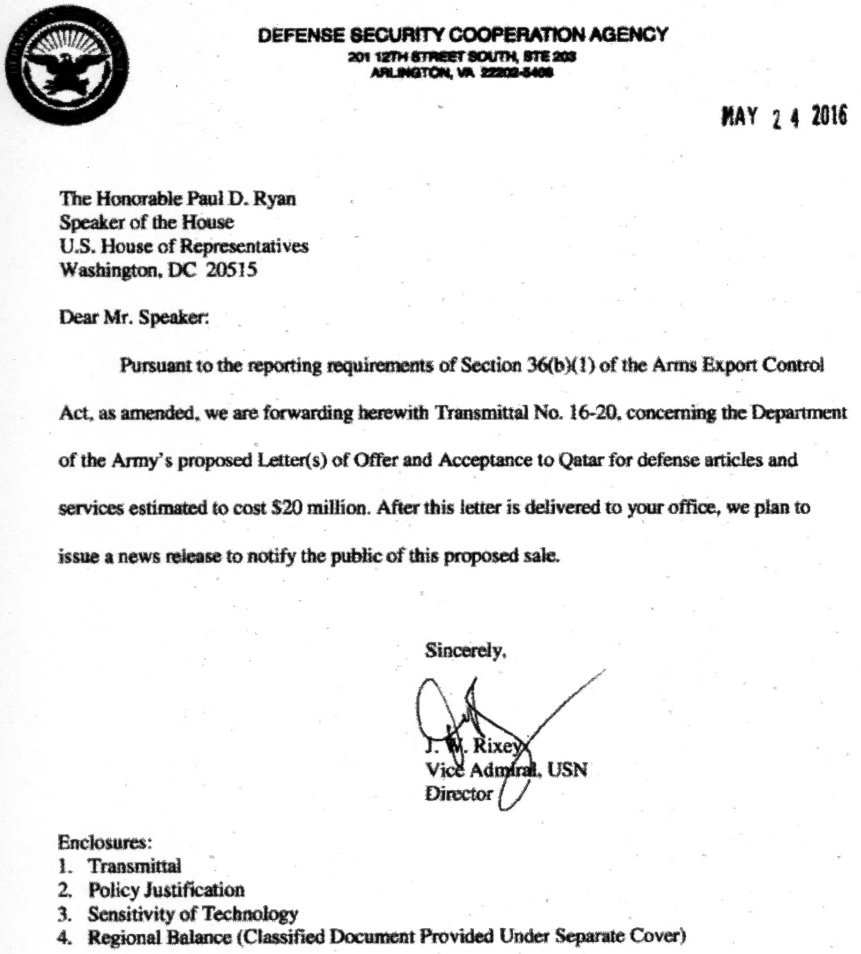
FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–20 with attached Policy Justification and Sensitivity of Technology.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 24 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-20, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Qatar for defense articles and services estimated to cost $20 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 16–20

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Government of Qatar

(ii) *Total Estimated Value:*

Major Defense Equipment *	$15 million
Other	5 million
Total	20 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Fifty (50) Javelin Guided Missiles (Category I) with Containers; Ten (10) Command Launch Units (CLUs) with Integrated Day/Thermal Sights (Category III Sensitive) with Containers.

Non-MDE: Ten (10) Javelin Missile Simulation Rounds, one (1) Enhanced Basic Skills Trainer (EPBST), and twelve (12) Batteries, Non-Rechargeable, six (6) Batteries, Storage, Rechargeable, Battery Discharger, Battery Charger for #9, and ten (10) Battery Coolant Units. Also included in this possible sale are U.S. Government Technical Information and Assistance and Life Cycle Contractor support (LCCS) for twenty-four (24) months or until funds are exhausted. This support provides for personnel, services, materials, facilities, equipment, maintenance, supply support, Integrated Support Plan, product assurance, and configuration management. The estimated cost is $20 million.

(iv) *Military Department:* U.S. Army.

(v) *Prior Related Cases, if any:* QA–B–UAR–$113,894,777–11 SEP 14.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* 24 May 2016.

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Qatar—Javelin Guided Missiles

The Government of Qatar has requested a possible sale of fifty (50) Javelin Guided Missiles (Category I), and ten (10) Command Launch Units (CLUs) with Integrated Day/Thermal Sight (Category III Sensitive) with Container. Also included in this possible sale are: Ten (10) Javelin Missile Simulation Rounds, one (1) Enhanced Basic Skills Trainer (EPBST), and twelve (12) Battery, Non-Rechargeable, six (6) Battery, Storage, Rechargeable, Battery Discharger, Battery Charger for #9, and ten (10) Battery Coolant Units. Also included in this possible sale are U.S. Government Technical Information and Assistance and Life Cycle Contractor support (LCCS) for twenty-four (24) months or until funds are exhausted. This support provides for personnel, services, materials, facilities, equipment, maintenance, supply support, Integrated Support Plan, product assurance, and configuration management. The total estimated value of Major Defense Equipment is $15 million. The overall total estimated value is $20 million.

This proposed sale contributes to the foreign policy and national security of the United States by helping to improve the security of a regional partner. Qatar is an important force for political stability and economic progress in the Persian Gulf region. This proposed sale strengthens U.S. efforts to promote regional stability by enhancing the defense to a key U.S. ally.

The proposed sale will improve Qatar's capability to meet current and future threats and provide greater security for its critical oil and natural gas infrastructure. Qatar will use the enhanced capability to strengthen its homeland defense. Qatar will have no difficulty absorbing these missiles into its armed forces.

The proposed sale will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin, Troy, AL. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require multiple trips by U.S. Government and contractor representatives to travel to Qatar for up to twenty-four (24) months for equipment de-processing, fielding, system checkout, training, and technical logistics support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 16–20

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex—Item No. vii

(vii) Sensitivity of Technology:

1. The Javelin Weapon System is a medium-range, man-portable, shoulder-launched, fire-and-forget, anti-tank system for infantry, scouts, and combat engineers. It may also be mounted on a variety of platforms including vehicles, aircraft and watercraft. The system weighs 49.5 pounds and has a maximum range in excess of 2,500 meters. The system is highly lethal against tanks and other systems with conventional and reactive armors. The system possesses a secondary capability against bunkers.

2. Javelin's key technical feature is the use of fire-and-forget technology which allows the gunner to fire and immediately relocate or take cover. Additional special features are the top attack and/or direct fire modes, an advanced tandem warhead and imaging infrared seeker, target lock-on before launch, and soft launch from enclosures or covered fighting positions. The Javelin missile also has a minimum smoke motor thus decreasing its detection on the battlefield.

3. The Javelin Weapon System comprises two major tactical components, which are a reusable Command Launch Unit (CLU) and a round contained in a disposable launch tube assembly. The CLU incorporates an integrated day-night sight that provides a target engagement capability in adverse weather and countermeasure environments. The CLU may also be used in a stand-alone mode for battlefield surveillance and target detection. The CLU's thermal sight is a second generation Forward-Looking Infrared (FLIR) sensor. To facilitate initial loading and subsequent updating of software, all on-board missile software is uploaded via the CLU after mating and prior to launch.

4. The missile is autonomously guided to the target using an imaging infrared seeker and adaptive correlation tracking algorithms. This allows the gunner to take cover or reload and engage another target after firing a missile. The missile has an advanced tandem warhead and can be used in either the top attack or direct fire modes (for targets undercover). An onboard flight computer guides the missile to the selected target.

5. The Javelin Missile System hardware and the documentation are UNCLASSIFIED. The missile software which resides in the CLU is considered SENSITIVE. The sensitivity is primarily in the software programs which instruct the system how to operate in the presence of countermeasures. The overall hardware is also considered SENSITIVE in that the infrared wavelengths could be useful in attempted countermeasure development. The benefits to be derived from the sale, as outlined in the Policy Justification of the notification, outweigh the potential damage that could result if sensitive technology was revealed to unauthorized persons.

6. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

7. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Qatar.

[FR Doc. 2016–15518 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–25]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

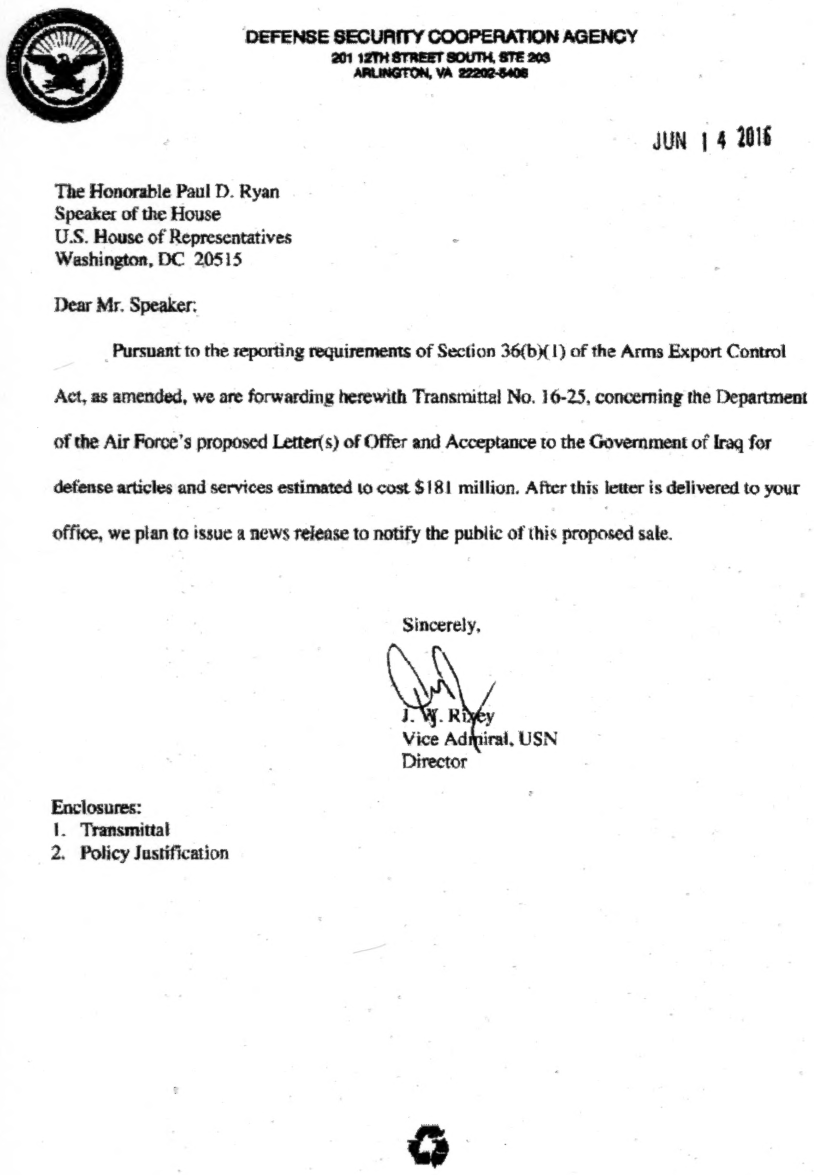
The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–25 with attached Policy Justification.

Dated: June 24, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLIING CODE 5001–06–P



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 14 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-25, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Iraq for defense articles and services estimated to cost $181 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification

BILLIING CODE 5001–06–C

Transmittal No. 16–25

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Government of Iraq

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0 million.
Other	$181 million.
Total	$181 million.

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Non-Major Defense Equipment (MDE): The Iraqi Air Force requests a five-year sustainment package for its AC–208 fleet that includes: Operational, intermediate, and depot-level maintenance; spare parts; component repair; publication updates; maintenance training; and logistics. Also included in this sale are Contract Logistics Services (CLS), training services, and Contract Engineering Services. There is no MDE associated with this possible sale. The total overall estimated cost is $181 million.

(iv) *Military Department:* Air Force

(v) *Prior Related Cases, if any:* IQ–D–QAH–$20M–13 FEB 09, IQ–D–QAF–$5M–26 OCT 08

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 14 June 2016

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

The Government of Iraq–AC–208 Sustainment, Logistics, and Spares Support

The Government of Iraq has requested a possible sale of a five-year sustainment package for its AC/RC–208 fleet that includes: Operational, intermediate, and depot-level maintenance; spare parts; component repair; publication updates; maintenance training; and logistics. Also included in this sale are Contract Logistics Services (CLS), training services, and Contract Engineering Services. There is no MDE associated with this possible sale. The total overall estimated value is $181 million.

The purchase of this sustainment package will allow the Iraqi Air Force (IqAF) to continue to operate its fleet of eight C–208 light attack and Intelligence, Surveillance, and Reconnaissance (ISR) aircraft beyond the June 2016 end of its existing CLS contract. Limited IqAF maintenance capability necessitates continued CLS. Ultimately, the goal is for the IqAF to become self-sufficient in the areas of aircraft maintenance and logistics training. Iraq will have no difficulty absorbing this support.

The proposed sale will contribute to the foreign policy and national security goals of the United States by helping to improve a critical capability of the Iraq Security Forces in defeating the Islamic State of Iraq and the Levant.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be Orbital ATK in Falls Church, Virginia, and Flight Safety International in Flushing, New York. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Iraq.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Iraq.

[FR Doc. 2016–15476 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–HA–0160]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Third Party Collection Program/Medical Services Account/Other Health Insurance; DD Form 2569; OMB Control Number 0720–0055.

Type of Request: Revision.

Number of Respondents: 3,900,000.

Responses per Respondent: 1.5.

Annual Responses: 5,850,000.

Average Burden per Response: 4 minutes.

Annual Burden Hours: 390,000.

Needs and Uses: The information collection requirement is necessary to obtain health insurance policy information used for coordination of health care benefits and billing third party payers and other federal agencies for health care provided to their beneficiaries and also to civilian non-Uniformed Service beneficiaries for health care provided to them. DoD implemented the Third Party Collection Program (TPCP) in FY87 based on the authority granted in 10 U.S.C. 1095 and implemented by 32 CFR 220 in accordance with the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) (Pub. L. 99–272, section 2001, April 7, 1986). Under the TPCP, DoD is authorized to collect from third-party payers the cost of inpatient and outpatient services rendered to DoD beneficiaries who have other health insurance. Military treatment facilities (MTFs) are required to make this form available to third-party payers upon request. A third-party payer may not request any other assignment of benefits form from the subscriber. Also, for civilian non-Uniformed Services beneficiary and interagency patients, DD Form 2569 is necessary and serves as an assignment of benefits, approval to submit claims to payers on behalf of the patient and authorization to release medical information.

Affected Public: Individuals and households.

Frequency: Annually.

Respondent's Obligation: Required to Obtain Benefits.

OMB Desk Officer: Ms. Stephanie Tatham.

Comments and recommendations on the proposed information collection should be emailed to Ms. Stephanie Tatham, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: June 24, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–15465 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–24]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

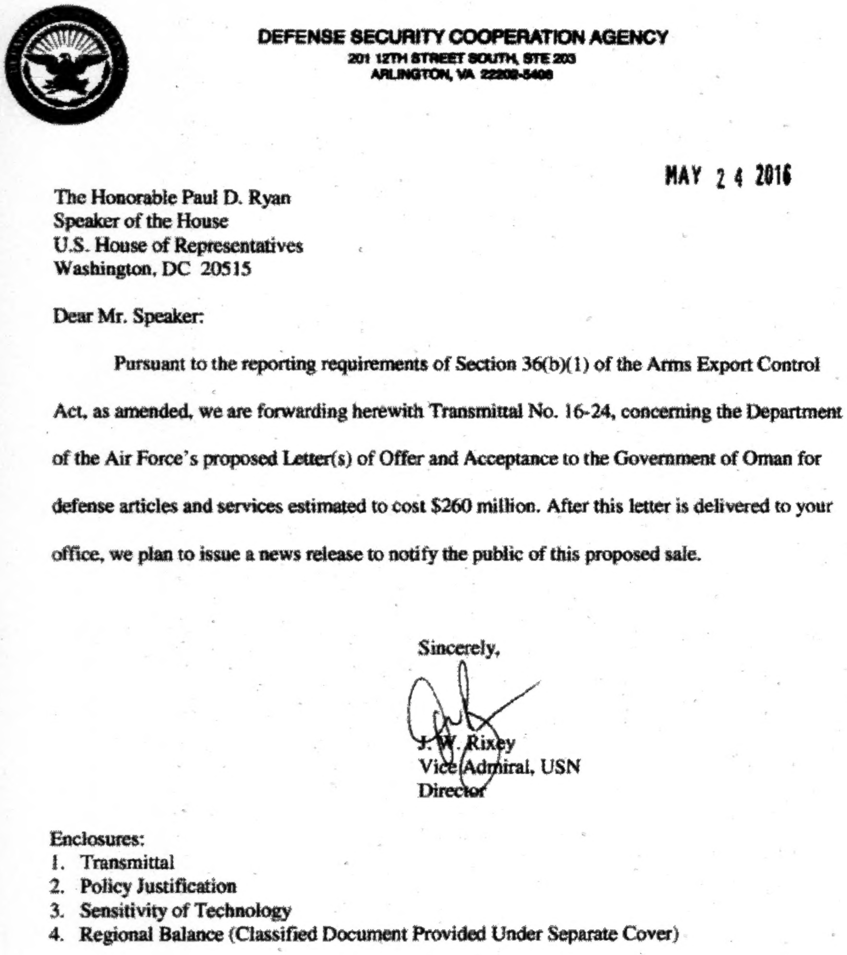
FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–24 with attached Policy Justification and Sensitivity of Technology.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 24 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-24, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Oman for defense articles and services estimated to cost $260 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 16–24

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Oman

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$0 million
Other	$260 million
Total:	$260 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Non-MDE: Follow-on support for Oman's existing F–16 fleet that includes support equipment, communications equipment, personnel training, spare and repair parts, publications, Electronic Combat International Security Assistance Program (ECISAP), Contractor Engineer Technical Services (CETS), Technical Coordination Group (TCG), International Engine Management Program (IEMP), Precision Measurement Equipment Laboratory (PMEL) calibration and technical orders. The estimated value of this possible sale is $260 million.

(iv) *Military Department:* USAF (QAO)

(v) *Prior Related Cases, if any:* MU–D–SDC—$693,191,686–5 June 2002; MU–D–QAJ—$186,003,411–22 September 2009; MU–D–SAB—$1,418,883,494–2 December 2011.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* 24 May 2016

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Oman-Continuation of Logistics Support Services and Equipment

The Government of Oman requests follow-on support for its existing F–16 fleet that includes support equipment, communications equipment, personnel training, spare and repair parts, publications, Electronic Combat International Security Assistance Program (ECISAP), Contractor Engineer Technical Services (CETS), Technical Coordination Group (TCG), International Engine Management Program (IEMP), Precision Measurement Equipment Laboratory (PMEL) calibration and technical orders. The estimated value of this possible sale is $260 million.

The proposed sale of support services will enable the Royal Air Force of Oman to ensure the reliability and performance of its F–16 aircraft. Oman will have no difficulty absorbing this support into its armed forces.

This proposed sale contributes to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been, and continues to be, an important force for political stability and economic progress in the Middle East.

The proposed sale allows the U.S. military to support the Royal Air Force of Oman, further strengthen the U.S.-Omani military-to-military relationship, and ensure continued interoperability of forces and opportunities for bilateral training and exercises with Oman's military forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors for this sale are: Lockheed Martin Aero, Fort Worth, TX; ITT (EXCELIS-Harris), Fort Wayne, IN; BAE Systems, Austin, TX; Honeywell, Clearwater, FL; Northrop Grumman, Linthicum Heights, MD; Marvin Engineering, Inglewood, CA; Lockheed Martin Missile and Fire Control, Orlando, FL; Goodrich Corp, Westford, MA. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale does not require the assignment of any additional U.S. Government or contractor representatives to Oman.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

All defense articles and services have been approved for release to the Government of Oman.

Transmittal No. 16–24

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. This case involves the sustainment of sensitive technology previously released to Oman in the sales of their F–16C/D aircraft. The F–16C/D Block 50/52 weapon system is UNCLASSIFIED, except as noted below. The aircraft uses the F–16 airframe and features advanced avionics and systems including the Pratt and Whitney F–100–PW–229 or the General Electric F–110–GE–129 engine, AN/APG–68V(9) radar, digital flight control system, external electronic warfare equipment, Advanced Identification Friend or Foe (AIFF), Link-16 datalink, and software computer programs.

2. Sensitive or classified (up to SECRET) elements of the proposed F–16C/D include hardware, accessories, components, and associated software: AN/APG–68V(9) Radar, Have Quick I/II Radios, AN/APX–113 AIFF with Mode IV capability, AN/ALE–47 Countermeasures (Chaff and Flare) set, LINK–16 Advanced Data Link Group A provisions only, Embedded Global Positioning System/Inertial Navigation System, Joint Helmet-Mounted Cueing System (JHMCS), ALQ–211(V)4 Advanced Integrated Defensive Electronic Warfare Suite (AIDEWS) without Digital Radio Frequency Memory, AN/ALQ–211(V)4 Countermeasures Set, Modular Mission Computer, Have Glass I/II without infrared top coat, and Digital Flight Control System. Additional sensitive areas include operating manuals and maintenance technical orders containing performance information, operating and test procedures, and other information related to support operations and repair. The hardware, software, and data identified are classified to protect vulnerabilities, design, and performance parameters and other similar critical information.

3. Software, hardware, and other data, which is classified or sensitive, is reviewed prior to release to protect system vulnerabilities, design data, and performance parameters. Some end-item hardware, software, and other data identified above are classified at the CONFIDENTIAL and SECRET level. Potential compromise of these systems is controlled through management of the basic software programs of highly sensitive systems and software-controlled weapon system on a case-by-case basis.

4. Oman is both willing and able to protect U.S. classified military information. Oman's physical and document security standards are equivalent to U.S. standards.

5. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification. Moreover, the benefits to be derived from this sale outweigh the potential damage that could result if the sensitive technology were revealed to unauthorized persons.

6. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Oman.

[FR Doc. 2016–15519 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 15–70]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

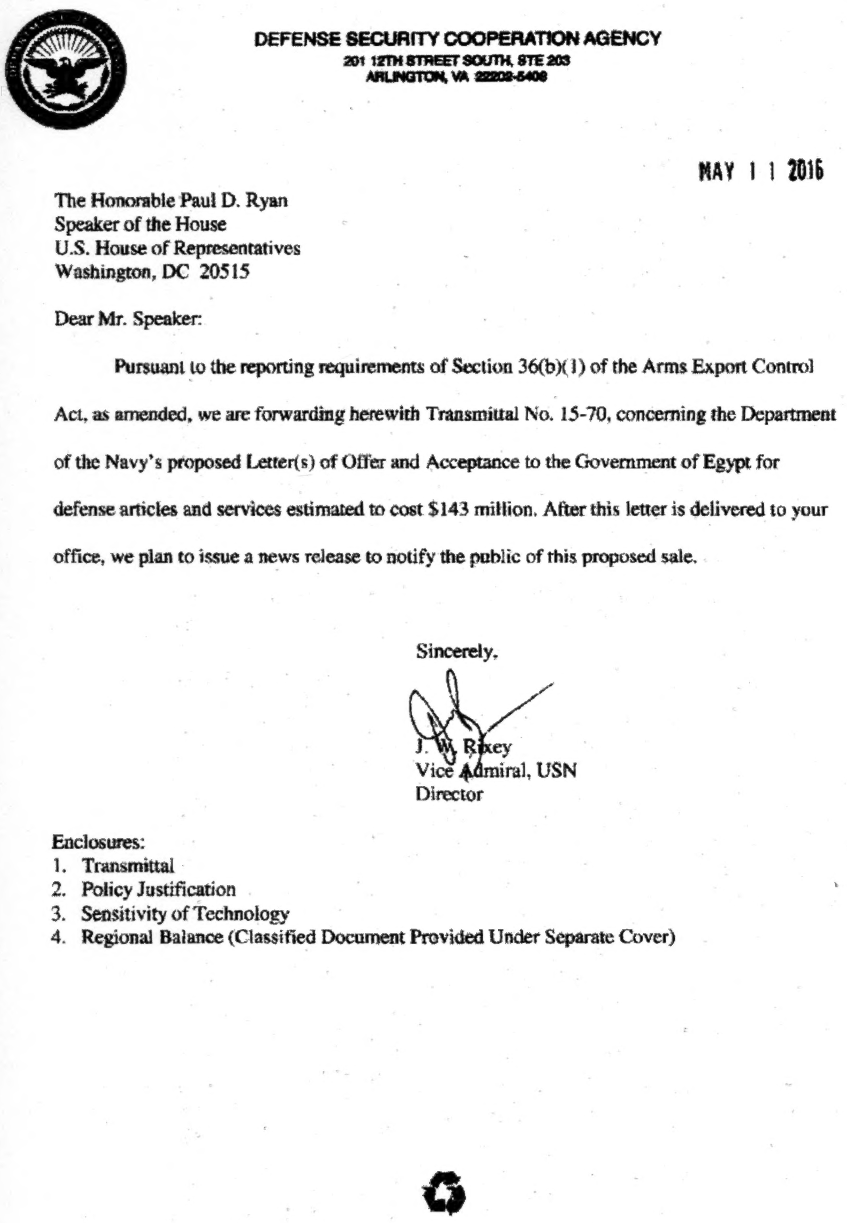
FOR FURTHER INFORMATION CONTACT: Chandelle K. Parker, DSCA/LMO, (703) 697–9027.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 15–70 with attached Policy Justification and Sensitivity of Technology.

Dated: June 27, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 1 1 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-70, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Egypt for defense articles and services estimated to cost $143 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 15–70

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(l) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Egypt

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$116 million
Other	$ 27 million
Total	$143 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE) includes:

Twenty (20) UGM–84L Harpoon Block II Encapsulated Missiles

Two (2) Encapsulated Harpoon Certification Training Vehicles (EHCTV)

Non-MDE items also included are containers, spare and repair parts, support and test equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor representative technical assistance, engineering and logistics support services, and other related elements of logistics support.

(iv) *Military Department:* Navy (XX–P–LFW)

(v) *Prior Related Cases, if any:*

FMS case ABW-$48M–12 Nov 97

FMS case ABZ-$68M–27 Mar 98

FMS Case CAN-$107M–22 Jan 03

(vi) *Sales Commission, Fee, etc., Paid, Offered. or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 11 May 2016

*as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Egypt—UGM–84L Harpoon Block II Encapsulated Missiles

The Government of Egypt has requested a possible sale of:

Major Defense Equipment (MDE) includes:

Twenty (20) UGM–84L Harpoon Block II Encapsulated Missiles

Two (2) Encapsulated Harpoon Certification Training Vehicles (EHCTV)

Non-MDE items also included are containers, spare and repair parts, support and test equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor representative technical assistance, engineering and logistics support services, and other related elements of logistics support.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a strategic partner that has been and continues to be an important force for political stability and economic progress in the Middle East.

The proposed sale of these submarine-launched missiles will support the Egyptian Navy's Type 209 submarines, increasing its anti-surface warfare and maritime security capabilities. Egypt already possesses Harpoon Block II missiles and will have no difficulty absorbing these additional weapons.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be The Boeing Company in St. Louis, Missouri. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require annual trips to Egypt involving U.S. Government and contractor representatives for technical reviews, support, and oversight for approximately five years.

There will be no adverse impact on United States defense readiness as a result of this proposed sale.

Transmittal No. 15–70

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(l) of the Arms Export Control Act

Annex Item

No. vii

(vii) *Sensitivity of Technology:*

1. The UGM–84L Harpoon Block II Encapsulated missile system is classified CONFIDENTIAL. The Harpoon missile is a conventional tactical weapon system currently in service in the U.S. Navy and in 29 other foreign nations. It provides day, night, and adverse weather, stand-off capability and is an effective Anti-Surface Warfare missile. The UGM–84L incorporates components, software, and technical design information that are considered sensitive. The following components of the proposed sale are classified CONFIDENTIAL:

a. The Radar Seeker

b. The Global Positioning System/Inertial Navigation System (GPS/INS)

c. Operational Flight Program Software

d. Missile operational characteristics and performance data

These elements are essential to the ability of the Harpoon missile to selectively engage hostile targets under a wide range of operations, tactical, and environmental conditions.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities. All defense articles and services listed in this transmittal have been authorized for release and export to Egypt.

[FR Doc. 2016–15515 Filed 6–29–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–76–000]

Transource Wisconsin, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On June 23, 2016, the Commission issued an order in Docket No. EL16–76–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of Transource Wisconsin, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *Transource Wisconsin, LLC,* 155 FERC ¶ 61,302 (2016).

The refund effective date in Docket No. EL16–76–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15559 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1434–000]

ISO New England Inc., New England Power Pool Participants Committee; Notice of Designation of Commission Staff as Non-Decisional

June 24, 2016.

With respect to the proceeding pending before the Commission in the above-captioned docket, the staff identified below from the Office of

Energy Policy and Innovation is designated as non-decisional in deliberations by the Commission in this docket. Accordingly, pursuant to 18 CFR 385.2202 (2015), staff will not serve as advisor to the Commission or take part in the Commission's review of any offer of settlement. Likewise, as non-decisional staff, pursuant to 18 CFR 385.2201 (2015), staff is prohibited from communicating with advisory staff concerning any deliberations in this docket.

The staff designated as non-decisional is:

- Daniel Kheloussi

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15561 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–75–000]

Xcel Energy Transmission Development Company, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On June 23, 2016, the Commission issued an order in Docket No. EL16–75–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of Xcel Energy Transmission Development Company, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *Xcel Energy Transmission Development Company, LLC,* 155 FERC ¶ 61,301 (2016).

The refund effective date in Docket No. EL16–75–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15558 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL16–78–000; QF90–203–007]

Saguaro Power Company, a Limited Partnership; Notice of Amendment

Take notice that on June 23 2016, Saguaro Power Company, A Limited Partnership submitted an amendment to its Petition for Waiver filed on June 6, 2016, providing an explanatory statement concerning its legal name in response to the Federal Energy Regulatory Commission's (Commission) staff inquiry.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comments: 5:00 p.m. Eastern Time on July 5, 2016.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15560 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2743–079]

Kodiak Electric Association, Inc.; Notice of Application Accepted for Filing, Ready for Environmental Analysis, Soliciting Comments, Motions To Intervene, Protests, Recommendations, Terms and Conditions, and Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of License.

b. *Project No.:* 2743–079.

c. *Date Filed:* May 26, 2016.

d. *Applicant:* Kodiak Electric Association, Inc.

e. *Name of Project:* Terror Lake Hydroelectric Project.

f. *Location:* The project is located on the Terror and Kizhuyak Rivers in Kodiak, Alaska. The project occupies federal lands administered by the U.S. Fish and Wildlife Service, Bureau of Land Management, and the U.S. Coast Guard.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Ms. Jennifer Richcreek, Kodiak Electric Association, Inc., P.O. Box 787, Kodiak, Alaska 99615–0787, (907) 654–7667.

i. *FERC Contact:* Dr. Jennifer Ambler (202) 502–8586 or *jennifer.ambler@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, recommendations, terms and conditions, and fishway prescriptions is 60 days from the issuance date of this notice by the Commission; reply comments are due 105 days from the issuance date of this notice by the Commission. The Commission strongly encourages electronic filing. Please file any motion to intervene, protest, comments, and/or recommendations using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal

Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2743–079.

k. *Description of Request:* The applicant proposes to construct two new diversion dams, each approximately 30 feet high and 250 feet wide, on eastern and western tributary branches of the West Fork of Hidden Basin Creek. Surface water from the diversion dam on the eastern tributary would flow through a half-mile-long, 5-foot-diameter underground pipe to the diversion dam on the western tributary. From there, the combined flow would travel by gravity through a 1.2-mile-long, 12-foot-diameter tunnel through the mountainous uplands of Kodiak Island to the Terror Lake reservoir. The applicant also proposes to construct a 4-mile-long spur road off of an existing road to provide access for constructing and maintaining the new diversions. The proposal would not change the authorized installed capacity of the project; however, it is expected to increase the average annual generation by 33,000 megawatt-hours. An additional 160 acres of land would be added to the project boundary. Most of the new facilities would be constructed on lands owned by the State of Alaska and on federal land already occupied by the project; however, a portion of the 1.2-mile-long tunnel would cross an additional 2 acres of federal land administered by the Kodiak National Wildlife Refuge outside of the project boundary.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title "COMMENTS", "PROTEST", "MOTION TO INTERVENE", "TERMS AND CONDITIONS" or "FISHWAY PRESCRIPTIONS" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the amendment. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15562 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–122–000.

Applicants: Hancock Wind, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Hancock Wind, LLC.

Filed Date: 6/24/16.

Accession Number: 20160624–5090.

Comments Due: 5 p.m. ET 7/15/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2331–056; ER10–2319–047; ER13–1351–029; ER10–2330–054; ER10–2317–047.

Applicants: J.P. Morgan Ventures Energy Corporation, BE Alabama LLC, BE CA LLC, Florida Power Development LLC, Utility Contract Funding, L.L.C.

Description: Notice of Non-Material Change in Status of the JPMorgan Sellers.

Filed Date: 6/22/16.

Accession Number: 20160622–5217.

Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: ER16–1232–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Response to Deficiency Letter per May 24, 2016 Order in Docket No. ER16–1232–000 to be effective 6/16/2016.

Filed Date: 6/23/16.

Accession Number: 20160623–5164.

Comments Due: 5 p.m. ET 7/14/16.

Docket Numbers: ER16–1995–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1636R16 Kansas Electric Power Cooperative, Inc. NITSA and NOA to be effective 9/1/2016.

Filed Date: 6/23/16.

Accession Number: 20160623–5162.

Comments Due: 5 p.m. ET 7/14/16.

Docket Numbers: ER16–1996–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2198R21 Kansas Power Pool NITSA NOA to be effective 9/1/2016.

Filed Date: 6/24/16.

Accession Number: 20160624–5040.

Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–1997–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1534R6 Kansas Municipal Energy

Agency NITSA NOA to be effective 6/1/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5042.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–1998–000.
Applicants: CalPeak Power—Border LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5044.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–1999–000.
Applicants: CalPeak Power LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5054.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2000–000.
Applicants: CalPeak Power—Enterprise LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5055.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2001–000.
Applicants: Malaga Power, LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5058.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2002–000.
Applicants: Midway Peaking, LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5059.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2003–000.
Applicants: CalPeak Power—Panoche LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5060.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2004–000.
Applicants: SEPG Energy Marketing Services, LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5061.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2005–000.
Applicants: PPL Electric Utilities Corporation.
Description: Notice of Cancellation of Transmission Interconnection Agreement Rate Schedule No. 39 of PPL Electric Utilities Corporation.
Filed Date: 6/24/16.
Accession Number: 20160624–5062.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2006–000.
Applicants: CalPeak Power—Vaca Dixon LLC.
Description: § 205(d) Rate Filing: Category 1 Seller Notice re SW & 819 to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5063.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2007–000.
Applicants: Saguaro Power Company, a Limited Partner.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5065.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2008–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1977R8 Nemaha-Marshall Electric Cooperative NITSA and NOA to be effective 9/1/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5070.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2009–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2014 Southwestern Power Administration Amendatory Agreement Fourth Extension to be effective 6/1/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5072.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2010–000.
Applicants: Hancock Wind, LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 8/24/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5096.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2011–000.
Applicants: Pennsylvania Electric Company, Jersey Central Power & Light, Metropolitan Edison Company, American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Penelec, JCPL, Met-Ed and ATSI submit SA Nos. 4221, 4222, 4223 and 4468 to be effective 1/31/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5119.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2012–000.
Applicants: The Narragansett Electric Company.
Description: § 205(d) Rate Filing: Filing of Indemnification Agreement with Deepwater Wind & Notice Waiver Request to be effective 5/10/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5134.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2013–000.
Applicants: FirstEnergy Solutions Corp.
Description: Compliance filing: Compliance filing 2016 June to be effective 6/1/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5162.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2014–000.
Applicants: ArcLight Energy Marketing, LLC.
Description: Market-Based Triennial Review Filing: Southwest Triennial & 819 Revisions to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5175.
Comments Due: 5 p.m. ET 8/23/16.

Docket Numbers: ER16–2015–000.
Applicants: Aragonne Wind LLC.
Description: Market-Based Triennial Review Filing: Southwest Triennial & 819 Revisions to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5180.
Comments Due: 5 p.m. ET 8/23/16.

Docket Numbers: ER16–2016–000.
Applicants: Buena Vista Energy, LLC.
Description: Market-Based Triennial Review Filing: Southwest Triennial & 819 Revisions to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5182.
Comments Due: 5 p.m. ET 8/23/16.

Docket Numbers: ER16–2017–000.
Applicants: Kumeyaay Wind LLC.
Description: Market-Based Triennial Review Filing: Southwest Triennial & 819 Revisions to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5183.
Comments Due: 5 p.m. ET 8/23/16.

Docket Numbers: ER16–2018–000.
Applicants: Mesquite Power, LLC.
Description: Market-Based Triennial Review Filing: Southwest Triennial & 819 Revisions to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5184.
Comments Due: 5 p.m. ET 8/23/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15554 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–18–000]

Magnum Gas Storage, LLC; Notice of Schedule for Environmental Review of The Magnum Gas Storage Amendment Project

On November 16, 2015, Magnum Gas Storage, LLC (Magnum) filed an abbreviated application to amend the Certificate of Public Convenience and Necessity granted by the Federal Energy Regulatory Commission (Commission or FERC) on March 17, 2011 in Docket No. CP10–22–000. Magnum was authorized to construct, own, and operate natural gas storage and transmission facilities in Millard, Juab, and Utah Counties, Utah. To date, construction of the authorized Magnum Gas Storage Project (Magnum Project) has not commenced.

On November 24, 2015, the Commission issued its Notice of Application for the Magnum Gas Storage Amendment Project (Amendment Project). Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Amendment Project.

Schedule for Environmental Review

Issuance of EA, July 29, 2016

90-day Federal Authorization Decision Deadline, October 27, 2016

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Amendment Project would result in the elimination and relocation of facilities within the original footprint of the Magnum Project. Specifically, Magnum would eliminate: Brine evaporation pond 1; monitoring wells DA–1 and DA–2; and monitoring wells, GA–1, GA–2, GA–9, GA–10, and GA–11. Magnum would also relocate: Four natural gas caverns; water wells 1 through 5; compression, dehydration, and pumping facilities; 4-inch gas supply line; maintenance and laydown area; office/warehouse building and substation; and site-wide utilities.

Additionally, Magnum would relocate a 6,252-foot-long segment of the 61.6-mile-long, 36-inch-diameter Header pipeline, 63 feet north of the authorized alignment, west of Jones Road in Millard County, Utah. Magnum is not proposing any changes to the temporary or permanent right-of-way width for this portion of the Header alignment. Therefore, the previously approved temporary and permanent disturbance acreage would not increase.

Background

On January 14, 2016, the Commission issued a *Notice of Intent To Prepare an Environmental Assessment for the Proposed Magnum Gas Storage Amendment Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received comments from the Hopi Tribe, the State of Utah Office of the Governor, and the State of Utah School and Institutional Trust Lands Administration (SITLA). The primary issues raised by the commentors are consultations on cultural resources, state permits, and the National Historic Perseveration Act. The U.S. Department of Transportation, SITLA, State of Utah, and Millard County, Utah, are cooperating agencies in the preparation of the EA for the Amendment Project.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC Web site (*www.ferc.gov*). Using the "eLibrary" link, select "General Search" from the eLibrary menu, enter the selected date range and "Docket Number" excluding the last three digits (*i.e.,* CP16–18), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15555 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11480–028]

Haida Energy, Inc.; Notice of Application Accepted For Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of License.

b. *Project No.:* 11480–028.

c. *Date Filed:* March 3, 2016.

d. *Applicant:* Haida Energy, Inc. (HEI).

e. *Name of Project:* Hiilangaay Hydroelectric Project.

f. *Location:* On Reynolds Creek, near the town of Hydaburg, Alaska.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Glen D. Martin, Alaska Power & Telephone Company, P.O. Box 3222, Port Townsend, WA 98368 (360) 385–1733 x122, Email: *glen.m@aptalaska.com.*

i. *FERC Contact:* Mr. M. Joseph Fayyad, (202) 502–8759, *Mo.Fayyad@ferc.gov,* and Marybeth Gay, (202) 502–6125, *Marybeth.Gay@ferc.gov.*

j. Deadline for filing comments, motions to intervene and protests, is 30 days from the issuance date of this notice. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, and recommendations, using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–11480–028.

k. *Description of Request:* HEI requests amendment of several provisions in its license for the unconstructed Híilangaay Hydroelectric Project, based on a Fish Habitat Permit issued by Alaska Department of Fish and Game and several factors it has identified that adversely affect the project economics. Specifically, based on consultations with state and federal agencies, HEI proposes a series of changes to the project description and affected license articles: (1) Move the penstock alignment further to the north; (2) move the location of the powerhouse about 80 feet further back from Reynolds Creek; (3) modify the tailrace length as a result of moving the powerhouse location; (4) add an access road to the diversion area on the south side of Rich's Pond; (5) adjust the proposed transmission line pole locations and widen the transmission line right of way in the Jumbo Island area to minimize tree-fall hazards to the transmission line; (6) increase the project's hydraulic capacity from 90 cfs to 100 cfs; (7) change the starting date for in-water construction window; (8) remove the "perched ledge" design requirement for the tailrace; (9) change the ramping rates requirement to apply only to flow decreases; (10) replace the requirement for a shunt pipeline with jet deflectors on the turbine and eliminate a synchronous bypass valve from the powerhouse design; and (11) change the fish screen design from a retractable T-cylinder screen to a conventional bar screen.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license surrender. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15563 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–470–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on June 17, 2016 Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, TX 77056, filed a prior notice request pursuant to sections 157.205 and 157.208(f)(2) of the Commission's regulations under the Natural Gas Act (NGA) Columbia's blanket certificate issued in Docket No. CP83–76–000.[1] Columbia seeks authorization to modify the Maximum Allowable Operating Pressure of various pipelines connected to Columbia's existing Waynesburg Compressor Station located in various counties in Pennsylvania, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Tyler R. Brown, Senior Counsel, Columbia Gas Transmission, LLC, 5151 San Felipe

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[1] *Columbia Gas Transmission Corporation* (predecessor to Columbia Gas Transmission, LLC), 22 FERC ¶ 62,029 (1983).

Suite 2500, Houston, TX 77056; telephone 713–386–3797; *jdowns@cpg.com*.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the "e-Filing" link. Persons unable to file electronically should submit original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15556 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–73–000]

Xcel Energy Southwest Transmission Company, LLC; Notice of Institution of Proceeding and Refund Effective Date

On June 23, 2016, the Commission issued an order in Docket No. EL16–73–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of Xcel Energy Southwest Transmission Company, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *Xcel Energy Southwest Transmission Company, LLC*, 155 FERC ¶ 61,300 (2016).

The refund effective date in Docket No. EL16–73–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: June 24, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15557 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0741; FRL–9947–16]

Product Cancellation Order for Certain Pesticide Registrations and Amendments To Terminate Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations and amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of products listed in Tables 1 and 2 of Unit II., pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a January 5, 2016 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 3 of Unit II. to voluntarily cancel and amend to terminate uses of these product registrations. In the January 5, 2016 **Federal Register** notice, EPA indicated that it would issue an order implementing the cancellations and amendments to terminate uses, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and amendments to terminate uses. This order will terminate the last alachlor products registered for use in the United States. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations and amendments are effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Miguel Zavala, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: 703–347–0504; email address: *zavala.miguel@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0741, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces the cancellations and amendments to delete uses, as requested by registrants, of 16 products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Product name	Active ingredient
100–1249	Adage Maxim 4FS Twin-Pak	Fludioxonil and Thiamethoxam.
524–314	Lasso Herbicide	Alachlor.
524–316	Lasso 94% Stabilized Technical	Alachlor.
524–329	Lariat Herbicide	Alachlor and Atrazine.
524–344	Micro-Tech Herbicide	Alachlor.
524–418	Bullet Herbicide	Alachlor and Atrazine.
524–523	MON 78746 Herbicide	Glyphosate-isopropylammonium and Quizalofop-p-ethyl.
7969–333	Agnique MMF Mosquito Larvicide & Pupicide	POE Isooctadecanol.
7969–334	Agnique MMF–GR Mosquito, Larvicide, & Pupicide	POE Isooctadecanol.
7969–340	Cando Poly Mosquito Film	POE Isooctadecanol.
10163–291	Thiophanate Methyl Technical 98.4	Thiophanate Methyl.
10163–292	Thiophanate Methyl Technical	Thiophanate Methyl.
83558–11	Pyrithiobac-sodium Technical	Pyrithiobac-Sodium.

TABLE 2—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE ONE OR MORE USES

Registration No.	Product name	Active ingredient	Use to be deleted
55260–4	Dodine Technical	Dodine	Strawberries.
55260–6	Syllit Flow Fungicide	Dodine.	
55260–11	Syllit 65WG	Dodine.	

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Tables 1 and 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed above.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS

EPA Company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300.
524	Monsanto Company, 1300 I Street NW., Suite 450 East, Washington D.C. 20005–7211.
7969	BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528.
10163	Gowan Company, P.O. Box 5569, Yuma, AZ 85366–5569.
55260	Agriphar S.A., 15401 Weston Parkway, Suite 150, Cary, NC 27513.
83558	ADAMA Celsius Property B.V. Amsterdam (NL), 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the January 5, 2016 **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations and amendments to delete uses of products listed in Tables 1 and 2 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested cancellations and amendments to terminate uses of the registrations identified in Tables 1 and 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Tables 1 and 2 of Unit II. are canceled or amended to terminate the affected uses. The effective date of the cancellations and amendments that are the subject of this notice is June 30, 2016. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the

Federal Register. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of January 5, 2016 (81 FR 236) (FRL–9937–07). The comment period closed on February 4, 2016.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

A. For Products 524–523, 10163–291, 10163–292, and 100–1249 in Table 1 of Unit II

The registrants have indicated to the Agency via written response that there are no existing stocks of these specific products. Therefore, no existing stocks date is necessary. Registrants are prohibited from selling or distributing these specific products listed in Table 1 of Unit II., except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal. Because products 524–523 and 100–1249 were not sold or marketed into the channels of trade, persons other than the registrant do not need an existing stocks period. Regarding products 10163–291 and 10163–292, while the registrant no longer has any inventory, persons other than the registrants may sell, distribute, or use existing stocks of the affected canceled products until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

B. For All Other Products Identified in Table 1 of Unit II

The registrants may continue to sell and distribute existing stocks of all other products listed in Table 1 of Unit II. until June 30, 2017, which is 1-year after the publication of the Cancellation Order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II., except for export in accordance with FIFRA section 17 (7 U.S.C. 136o) or for purposes of proper disposal.

Persons other than the registrants may sell, distribute, or use existing stocks of the affected canceled products until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

C. For All Products Identified in Table 2 of Unit II

Now that EPA has approved product labels reflecting the requested amendments to delete uses, registrants are permitted to sell or distribute products listed in Table 2 of Unit II. under the previously approved labeling until January 2, 2018, a period of 18 months after publication of the cancellation order in this **Federal Register**, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the deleted uses identified in Table 2 of Unit II., except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for purposes of proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of the products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the products with the terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 13, 2016.

Michael Goodis,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–15616 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0310; FRL–9947–25]

Plant-Incorporated Protectants: Proposed Modification of Registration Procedures for Plant-Incorporated Protectants in Breeding Line Intermediates; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is making available for comment a White Paper describing how the Agency is proposing to modify its current approach to plant-incorporated protectants (PIPs) in breeding line intermediates (BLIs) under Section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). A PIP is a type of pesticide intended to be produced and used in a living plant, or the produce thereof. A BLI is an intermediate used in plant breeding to bring together, or "stack," two or more PIPs that have each been individually engineered into different lines of a seed propagated plant. These proposed changes are intended to bring efficiencies to the Agency's approach to PIPs in BLIs while not reducing EPA's ability to ensure that PIPs in BLIs meet the requirements of FIFRA.

DATES: Comments must be received on or before August 15, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2016–0310, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology that may develop and market plant-incorporated protectants. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 32532) *e.g.,* establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals;

- Food Processing (NAICS code 311) transforming agricultural products into products for immediate or final consumption;
- Crop Production (NAICS code 111) *e.g.,* establishments primarily engaged in growing crops, plants, vines or trees and their seeds;
- Colleges, Universities and Professional Schools (NAICS code 611310) *e.g.,* establishments of higher learning which are engaged in development and marketing of virus-resistant plants;
- Research and Development in the Physical, Engineering and Life Sciences (NAICS code 54171) *e.g.,* establishments primarily engaged in conducting research in the physical, engineering or life sciences, such as agriculture and biotechnology.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

C. How can I get copies of this document and other related information?

A copy of the White Paper Concerning Registration of Plant-Incorporated Protectants for Use in Breeding Line Intermediates to Produce Stacked Products is available in the docket under docket identification (ID) number EPA–HQ–OPP–2016–0310.

II. What action is the Agency taking?

EPA is making available for comment a White Paper describing a proposed modification of its approach to regulation of plant-incorporated protectants (PIPs) in breeding line intermediates (BLIs) under Section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This modification is proposed in light of the increasing use of BLIs to stack together several different PIPs during seed production.

A plant-incorporated protectant (PIP) is a type of pesticide defined at Title 40 of the Code of Federal Regulations as "intended to be produced and used in a living plant, or the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or the produce thereof." BLIs are an integral part of the process used to bring together, using conventional breeding in seed production, two or more PIPs that have each been individually engineered into different lines of a seed propagated plant. EPA's proposed modification of its approach to regulation of PIPs in BLIs is a refocusing of the Agency's use of its authority to regulate pesticides, and maintains EPA's ability to ensure that PIPs in BLIs meet the requirements of FIFRA.

The White Paper describes how the Agency proposes to refocus its authority to regulate PIPs in BLIs. Currently, each combination of PIPs in BLIs must have a unique registration before it can be sold or distributed in commerce. Under the proposal described in the White Paper, rather than requiring a unique registration for each BLI combination, EPA would regulate PIPs in BLIs through the terms and conditions imposed on the registrations issued for each PIP to be combined through the use of BLIs in the stacked commercial PIP product. Such registrations would control which PIPs can be used in which BLIs and how the PIPs in BLIs can be used. Under the proposed approach, EPA would continue to assess PIPs in BLIs for potential risk and continue to use its FIFRA authorities to ensure safe use of PIPs in BLIs.

EPA's proposed modifications would introduce changes into its approach to PIPs in BLIs that are intended to reduce administrative costs for both the Agency and for companies using BLIs to stack several PIPs together in a single product. The proposed modification is directed solely at PIPs in BLIs used for the purpose of producing seed and is not intended to change EPA's approach to issuance of unique registrations for PIPs intended for full commercial sale and distribution. A full copy of the White Paper is available in docket EPA–HQ–OPP–2016–0310.

EPA requests comment on the proposal as a whole and on the various aspects of the proposal from both the public and industry, including seed companies, farmers, grain dealers, food processors and grocery manufacturers. EPA is specifically seeking comment from state regulatory officials on how this proposed approach might affect their approach to pesticide regulation. EPA asks comment on the extent to which this type of approach to PIPs in BLIs relieves administrative burden and cost for the regulated community, and how frequently registrants are likely to use such an approach. EPA also requests comment on how the proposed approach would affect efficiency and cost savings, in light of the commercial seed production landscape created by the licensing of intellectual property in the form of PIPs. EPA also asks farmers, grain dealers, food processors and grocery manufacturers whether this proposed change in approach could affect their activities, including possible effects on trade, and if yes, how.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 14, 2016.

Mark A. Hartman,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–15615 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0657; FRL–9946–31–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Flexible Vinyl and Urethane Coating and Printing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), "NSPS for Flexible Vinyl and Urethane Coating and Printing (40 CFR part 60, subpart FFF) (Renewal)" (EPA ICR No. 1157.11, OMB Control No. 2060–0073), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through June 30, 2016. Public comments were previously requested via the **Federal Register** (80 FR 32116) on June 5, 2015, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller

description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before August 1, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0657, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and recordkeeping requirements for the general provisions of 40 CFR part 60, subpart A, as well as for the specific requirements at 40 CFR part 60 subpart FFF. This includes submitting initial notification reports, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/Affected Entities: Flexible vinyl and urethane coating and printing facilities.

Respondent's Obligation to Respond: Mandatory (40 CFR part 60, subpart FFF).

Estimated Number of Respondents: 25 (total).

Frequency of Response: Initially and semiannually.

Total Estimated Burden: 848 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total Estimated Cost: $320,000 (per year), which includes $232,000 in both annualized capital/startup and operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the respondent burden and cost, including total O&M cost, in this ICR. This is not due to program changes; rather, it is due to an increase of one additional source being subject to these regulations since the last ICR renewal period. In addition, this ICR assumes all existing sources will need to re-familiarize themselves with the regulation each year. This change in assumption also contributes to an increase in the labor hours and costs.

Dated: June 23, 2016.

Matthew Leopard,

Director, Office of Information Collection.

[FR Doc. 2016–15567 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0349; FRL–9948–17]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 2-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review a set of scientific issues being considered by the Environmental Protection Agency regarding the human health and ecological risk assessments for SmartStax PRO (MON 89034 x TC1507 x MON 87411 x DAS–59122–7), a plant-incorporated protectant intended to control corn rootworm through ribonucleic acid (RNA) interference.

DATES: The meeting will be held on September 27–28, 2016, from approximately 9:00 a.m. to 5:00 p.m.

Comments. The Agency encourages written comments be submitted on or before September 13, 2016, to provide adequate time for the FIFRA SAP to review and consider the comments. The Agency encourages requests for oral comments be submitted on or before September 20, 2016. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after September 13, 2016, should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION.**

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before August 1, 2016.

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP Web site at *http://www.epa.gov/sap* for information on how to access the meeting webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES:

Meeting: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2016–0349, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or

delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

Nominations, requests to present oral comments, and requests for special accommodations. Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Steven Knott, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–0103; email address: *knott.steven@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

C. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA–HQ–OPP–2016–0349 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages written comments be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before September 13, 2016, to provide FIFRA SAP the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after September 13, 2016, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT.** Anyone submitting written comments at the meeting should bring 15 copies for distribution to FIFRA SAP by the DFO.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to FIFRA SAP to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before September 20, 2016, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 15 copies of his or her comments and presentation for distribution to FIFRA SAP at the meeting by the DFO.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: Ecological risk assessment, human health risk assessment, entomology, bioinformatics, RNAi technology, biotechnology, plant breeding and genomics, and molecular biology. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, email address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before August 1, 2016. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before that date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the Panel and the expertise needed to address the Agency's charge to the Panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a federal department or agency, or their employment by a federal department or agency except EPA. Other factors considered during the selection process include availability of the potential Panel member to fully participate in the Panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on the FIFRA SAP. Numerous qualified candidates are identified for each Panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. The Agency anticipates selecting approximately eight ad hoc scientists to have the collective breadth of experience needed to address the Agency's charge for this meeting.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634—Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidates' employment, stocks, bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a lack of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on the FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP Web site at *http://www.epa.gov/sap* or may be obtained from the OPP Docket at *http://www.regulations.gov.*

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix). FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA established a Science Review Board (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism, FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of the FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendations to the Agency.

B. Public Meeting

The use of RNA interference (RNAi) gene silencing technology, particularly RNAi for pesticidal purposes to control macroorganism pests, is a relatively recent innovation. Post-transcriptional silencing of gene function is a very rapid process where double-stranded RNA (dsRNA) directs sequence-specific degradation of a RNA. As EPA anticipated receiving pesticide applications based on RNAi technologies and identified the need to better understand the scientific issues concerning the assessment of the risks to human health and the environment that RNAi technologies pose, it convened a January 28, 2014, Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP). This FIFRA SAP provided EPA with scientific advice regarding the framework for assessing RNAi pesticide products.

On October 29, 2015, EPA registered MON 87411, a corn plant-incorporated protectant (PIP) for seed increase/breeding purposes only and not for commercial release, with a time limitation of 2 years and a per-season acreage cap of 15,000 acres. In addition to Bacillus thuringiensis (Bt) Cry3Bb1 protein, MON 87411 expresses DvSnf7 dsRNA. Upon consumption by corn rootworm (CRW), the insect's RNAi machinery recognizes DvSnf7 dsRNA, resulting in down-regulation of the targeted DvSnf7 gene and leading to CRW mortality. Earlier this year, EPA received applications from Monsanto Company and Dow AgroSciences, LLC, requesting registration of commercial release RNAi PIPs expressing DvSnf7 dsRNA and known by the name SmartStax PRO. SmartStax PRO also expresses several Bt insecticidal Cry proteins.

EPA will present the human health risk assessment conducted for DvSnf7 dsRNA, as expressed in SmartStax PRO, and will consider the fate of ingested dsRNA and the potential for impacts on gene expression and the immune system. The action of a RNA interference construct relies upon some level of sequence homology with the target gene transcript; however, the fidelity of the sequence match may vary in some instances. EPA will discuss the role that bioinformatic analysis may play in understanding and predicting possible off-target effects within the host genome, as well as in predicting nontarget effects as part of the ecological risk assessment.

EPA will also present an ecological risk assessment for DvSnf7 dsRNA, as expressed in SmartStax PRO, and will include descriptions of environmental fate and nontarget exposure, data reviewed in support of the risk assessment, risk characterization and description, and uncertainties. The charge to the panel will request expert opinion on completeness of the data set and uncertainties related to the risk conclusions.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (*i.e.,* members and ad hoc members for this meeting), and the meeting agenda will be available by approximately late August. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available at *http://www.regulations.gov* and the FIFRA SAP Web site at *http://www.epa.gov/sap.*

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted to the FIFRA SAP Web site or may be obtained from the OPP Docket at *http://www.regulations.gov.*

Authority: 7 U.S.C. 136 *et seq.;* 21 U.S.C. 301 *et seq.*

Dated: June 23, 2016.

Stanley Barone,

Acting Director, Office of Science Coordination and Policy.

[FR Doc. 2016–15589 Filed 6–29–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Deletion of Items From Sunshine Act Meeting

June 24, 2016.

The following items have been deleted from the list of items scheduled for consideration at the Friday, June 24, 2016, Open Meeting and previously listed in the Commission's Notice of June 17, 2016. Items 1, 2, 4, 5, 6, and 7 on the consent agenda have been adopted by the Commission.

2. *Public Safety & Homeland Security Bureau:*
   Title: Amendment of Part 11 of the Commission's Rules Regarding the Emergency Alert System (PS Docket No. 15–94)
   Summary: The Commission will consider a Report and Order that would revise the Emergency Alert System rules by adding new event codes covering extreme high winds and storm surges caused by Category 3 (and greater) hurricanes.

* * * * *

Consent Agenda

The Commission will consider the following subjects listed below as a consent agenda and these items will not be presented individually:

1. *Media:*
   Title: The Los Angeles Social Justice Radio Project, Application for a Permit to Construct a New Low Power FM Station at Los Angeles, California.
   Summary: The Commission will consider a Memorandum Opinion and Order concerning the dismissal of an application to construct a new low power FM station in Los Angeles, California.
2. *Media:*
   Title: LPFM MX Group 37.
   Summary: The Commission will consider a Memorandum Opinion and Order concerning the LPFM MX Group 37 (San Francisco, CA) from the 2013 LPFM filing window.
3. *Media:*
   Title: Comparative Consideration of 3 Groups of Mutually Exclusive Applications for Permits to Construct New Noncommercial Educational FM Stations.
   Summary: The Commission will consider a Memorandum Opinion and Order concerning three petitions for reconsideration for permits to construct new NCE FM stations.
4. *Media:*
   Title: Kingdom of God, Inc., Former Licensee of Deleted Class A Television Station DWKOG–LP, Indianapolis, IN.
   Summary: The Commission will consider a Memorandum Opinion and Order concerning the denial of a Petition for Reconsideration of the cancellation of the Station's license and digital construction permit, deletion of its call-sign, and dismissal of pending applications.
5. *Media:*
   Title: Royce International Broadcasting Company, Assignor, and Entercom Communications Corp. (Assignee), Application for Assignment of License of Station KUDL(FM) (formerly KWOD), Sacramento, California.
   Summary: The Commission will consider a Memorandum Opinion and Order concerning the Media Bureau's dismissal of a Petition for Review.
6. *Media:*
   Title: Gwendolyn May, Former Permittee of Deleted Low Power Television Station DK15CC, San Antonio, TX.
   Summary: The Commission will consider a Memorandum Opinion and Order concerning the denial of a Petition for Reconsideration regarding the rescission of the Video Division's grant of for application for assignment of a construction permit.
7. *Media:*
   Title: R&F Broadcasting, Inc. Licensee of Station WRFB(TV), Carolina, Puerto Rico.
   Summary: The Commission will consider an Order adopting a Consent Decree which resolves issues regarding potential violations of the Commission's rules and grants the license renewal application of WRFB(TV).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–15451 Filed 6–29–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Friday, July 22, 2016, from 8:30 a.m. to 2:45 p.m.

ADDRESSES: The meeting will be held at AHRQ, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland 20857, (301) 427–1456. For press-related information, please contact Alison Hunt at (301) 427–1244 or *Alison.Hunt@ahrq.hhs.gov.*

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827–4840, no later than Friday, July 15, 2016. The agenda, roster, and minutes will be available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Campbell's phone number is (301) 427–1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ, on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Friday, July 22, 2016, there will be a subcommittee meeting for the National Healthcare Quality and Disparities Report scheduled to begin at 7:30 a.m. This meeting is open to the public. The Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting agenda includes an update on AHRQ's current research, programs, and initiatives, an update on the synthesis of evidence and a presentation on AHRQ's role in quality measurement. The final agenda will be available on the AHRQ Web site at *www.AHRQ.gov* no later than Friday, July 15, 2016. The meeting is open to the public and will be available via webcast at *www.webconferences.com/ahrq.*

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2016–15487 Filed 6–29–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10260, CMS–10305 and CMS–10622]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by August 29, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ______, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10260 Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3)
CMS–10305 Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g))
CMS–10622 Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); *Use:* We require that Medicare Advantage (MA) organizations and Part D sponsors use standardized documents to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Social Security Act (Act) and 42 CFR 422.111(b) for MA organizations, and section 1860D–1(c) of the Act and 42 CFR 423.128(a)(3) for Part D sponsors. The regulatory provisions require that MA organizations and Part D sponsors disclose plan information, including: Service area, benefits, access, grievance and appeals procedures, and quality improvement and quality assurance requirements by September 30th of each year. The MA organizations and Part D sponsors use the information to comply with the disclosure requirements. We will use the approved standardized documents to ensure that correct information is disclosed to current and potential enrollees.

For 2017, CMS has a total of nine standardized ANOC/EOC documents: Health Maintenance Organization, Cost, Dual Eligible Special Needs, Medicare Medical Savings Account, Private-Fee-For-Service, Preferred Provider Organizations, Preferred Provider Organization with Prescription Drugs, Health Maintenance Organization with Prescription Drug, and Prescription Drug. These standardized documents will be used by MA organizations and Part D sponsors for the 2018 contract year.

In revising the standardized ANOC/EOCs for contract year 2018, we did not add to or remove any section from the prior contract year ANOC/EOC models. MA organizations and Part D sponsors are still required to use the standardized language in the ANOC/EOC models and to send this document to current members at least 15 days prior to the start of the annual enrollment period or by September 30, 2017 for the 2018 enrollment season, based on 42 CFR 422.111(a) (3) and 423.128(a)(3). *Form Number:* CMS–10260 (OMB control number: 0938–1051); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 805; *Total Annual Responses:* 805; *Total Annual Hours:* 9,660. (For policy questions regarding this collection contact Gladys Valentin at 410–786–1620.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g)); *Use:* Organizations contracted to offer

Medicare Part C and Part D benefits are required to report data to us on a variety of measures. For the data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To meet this goal, we have developed reporting standards and data validation specifications with respect to the Part C and Part D reporting requirements. These standards provide a review process for Medicare Advantage Organizations, Cost Plans, and Part D sponsors to use to conduct data validation checks on their reported Part C and Part D data.

The FDCF is revised for the 2017 and 2018 DV collection periods by changing the scoring of six standards from a binary scale to a five-point Likert-type scale. This change is expected to improve the precision of the data validation scores by increasing overall variation in total scores among the MAOs and PDPs. The revision is not expected to alter resource requirements, since the assessment by DV contractors in scoring standards will continue to be based on the percentage of records that meet the standards. *Form Number:* CMS–10305 (OMB control number: 0938–1115); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 639; *Total Annual Responses:* 639; *Total Annual Hours:* 209,271. (For policy questions regarding this collection contact Terry Lied at 410–786–8973.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes; *Use:* As mandated by Sections 1152–1154 of the Social Security Act, CMS directs the QIO program, one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries. In the 11th SOW, CMS restructured the QIO program to funded Quality Innovation Networks (QIN)–QIOs, Beneficiary and Family-Centered Care (BFCC) organizations, National Coordinating Centers (NCCs), Program Collaboration Centers (PCCs), and the Strategic Innovation Engine (SIE). In the current SOW, 14 QIN–QIOs coordinate the work of 53 QIOs nationwide including all 50 states and other U.S. territories.

CMS evaluates the quality and effectiveness of the QIO program as authorized in Part B of Title XI of the Social Security Act. CMS created the Independent Evaluation Center (IEC) to provide CMS and its stakeholders with an independent and objective program evaluation of the 11th SOW. Evaluation activities will focus on analyzing how well the QIO program is achieving the three aims of better care, better health, and lower cost as well as the effectiveness of the new QIO program structure. One of the QIN–QIOs' tasks to achieve these three aims is to support participating nursing homes in their efforts to improve quality of care and health outcomes among residents. According to the 2013 CMS Nursing Home Data Compendium, more than 15,000 nursing homes participated in Medicare and Medicaid programs with more than 1.4 million beneficiaries resided in U.S. nursing homes. These residents and their families rely on nursing homes to provide reliable, safe, high quality care. However, cognitive and functional impairments, pain, incontinence, antipsychotic drug use, and healthcare associated conditions (HAC), such as pressure ulcers and falls, remain areas of concern.

This information collection is to provide data to assess QIN–QIOs efforts aimed at addressing these HACs in nursing homes. QIN–QIOs are responsible for recruiting nursing homes to participate in the program. We will conduct an annual survey of administrators of nursing homes participating in the QIN–QIO program (intervention group) and administrators at nursing homes that are not participating in the QIN–QIO program (comparison group). Our proposed survey assesses progress towards the goals of the QIN–QIO SOW, including activities and strategies to increase mobility among residents, reduce infections, reduce use of inappropriate antipsychotic medication among long-term stay residents.

We plan to conduct qualitative interviews with nursing home administrators. This interview will supplement the Nursing Home Survey and provide more in-depth contextual information about the QIN–QIO program implementation within at nursing homes, including: (i) Their experience with, and perceived success of QIN–QIO collaboratives; (ii) their satisfaction with the QIN–QIO Collaborative and QIO support; (iii) perceived value and impact of QIO program; and (iv) drivers and barriers to QIN–QIO involvement and success.

Information from QIO leadership and/or state/territory task leads will be collected by interviews and focus groups. Interviews with Nursing Home Task leaders at the QIN and QIO will be conducted in-person during site visits and/or over the phone. We will conduct focus groups with QIO-level Directors during the annual CMS Quality conference. The purpose of the interviews and focus groups is to examine: (i) QIO processes for recruiting nursing homes, peer coaches, and beneficiaries to participate in the program; (ii) strengths and challenges of QIN–QIO activities related to nursing homes; (iii) partnership and coordination with other QIN–QIO tasks; and (iv) overall lessons learned. We will also conduct qualitative interviews with nursing home peer coaches. *Form Number:* CMS–10622 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Business or other for-profits and Not-for Profits institutions; *Number of Respondents:* 856; *Total Annual Responses:* 856; *Total Annual Hours:* 242. (For policy questions regarding this collection contact Robert Kambic at 410–786–1515.)

Dated: June 27, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–15564 Filed 6–29–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10316 and CMS–10545]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to

enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *August 1, 2016.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* This data collection complements the satisfaction data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems survey by providing dissatisfaction data in the form of reasons for disenrollment from a Prescription Drug Plan. The data collected in this survey can be used to improve the operation of Medicare Advantage (MA) (both MA and MA–PD) contracts and standalone prescription drug plans (PDPs) through the identification of beneficiary disenrollment reasons. Plans can use the information to guide quality improvement efforts. The data can also be used by beneficiaries who need to choose among the different MA and PDP options. To the extent that these data identify areas for improvement at the contract level they can be used for contract oversight. *Form Number:* CMS–10316 (OMB control number: 0938–1113); *Frequency:* Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 56,972; *Total Annual Responses:* 56,972; *Total Annual Hours:* 15,032. (For policy questions regarding this collection contact Beth Simon at 415–744–3780.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10; *Use:* Home health agencies (HHAs) are required to collect the outcome and assessment information data set (OASIS) to participate in the Medicare program. The OASIS item set has been revised and is now referred to as OASIS–C2. It is scheduled for implementation on January 1, 2017. The OASIS C2 is being modified to include changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act), and formatting changes throughout the document. *Form Number:* CMS–10545 (OMB control number: 0938–1279); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 12,198; *Total Annual Responses:* 17,900,000; *Total Annual Hours:* 15,812,511. (For policy questions regarding this collection contact Michelle Brazil at 410–786–1648).

Dated: June 27, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–15549 Filed 6–29–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; State Annual Long-Term Care Ombudsman Report Amended Data Collection

AGENCY: Administration for Community Living, Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Community Living, Administration on Aging (ACL/AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to conflict of interest reporting per the Code of Federal Regulations and Older Americans Act Title VII.

DATES: Submit written or electronic comments on the collection of information by August 29, 2016.

ADDRESSES: Submit electronic comments on the collection of information to: *louise.ryan@acl.hhs.gov.*

Submit written comments on the collection of information to: U.S. Department of Health and Human Services: Administration for Community Living 701 Fifth Avenue, Suite 1600 M/S RX–33, Seattle, WA 98104, Attention: Louise Ryan.

FOR FURTHER INFORMATION CONTACT: Louise Ryan by telephone: (206) 615–2514 or by email: *louise.ryan@acl.hhs.gov*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL/AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Section 1327.21 (conflicts of interest) of the Long-Term Care Ombudsman Program rule requires the State agency and the Ombudsman to identify and take steps to remove or remedy organizational conflicts of interest between the Office and the State agency or other agency carrying out the Ombudsman program. Additionally the rule requires the Ombudsman to identify organizational conflicts of interest in the Ombudsman program and describe steps taken to remove or remedy conflicts within the annual report submitted to the Assistant Secretary through the National Ombudsman Reporting System. The proposed form and instructions are posted on the ACL/AoA Web site at: *http://www.aoa.acl.gov/AoA_Programs/Elder_Rights/Ombudsman/index.aspx.*

AoA estimates the burden of this additional collection of information as follows: Approximately 10 to 30 minutes per respondent, depending on the number of conflicts to report, with 52 state Ombudsman programs responding annually for a range of 8.6 to 26 hours.

Dated: June 23, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–15433 Filed 6–29–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0065]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the **Federal Register** of May 5, 2016. In the notice, FDA announced an opportunity for public comment on the proposed collection of certain information by the Agency. We are taking this action due to maintenance on the Federal eRulemaking portal from July 1 through July 5, 2016.

DATES: FDA is extending the comment period on the notice published May 5, 2016 (81 FR 27140). Submit either electronic or written comments by July 12, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2013–N–0065 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 5, 2016 (81 FR 27140), FDA published a notice giving interested persons until July 5, 2016, to comment on the information collection provisions of the Agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

From July 1 through July 5, 2016, the Federal eRulemaking Portal, *http://www.regulations.gov,* is undergoing maintenance. We are, therefore, extending the comment period for commenting on the information collection provisions of the Agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The extended comment period will close on July 12, 2016.

Dated: June 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15475 Filed 6–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1099]

Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice, published in the **Federal Register** of April 6, 2016 (81 FR 19976), announcing the availability of a draft guidance for industry entitled "Inorganic Arsenic in Rice Cereals for Infants: Action Level," a supporting document entitled "Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants," and a risk assessment report entitled "Arsenic in Rice and Rice Products Risk Assessment: Report." We are taking this action due to maintenance on the Federal eRulemaking portal in early July 2016.

DATES: Submit either electronic or written comments by July 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1099 for "Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 6, 2016 (81 FR 19976), FDA published a notice announcing the availability of a draft guidance for industry entitled "Inorganic Arsenic in Rice Cereals for Infants: Action Level," a supporting document entitled "Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants," and a risk assessment report entitled "Arsenic in Rice and Rice Products Risk Assessment: Report." Although you can comment on any guidance at any time, to ensure that we consider comments on this draft guidance before we begin work on the final version, interested persons were originally given until July 5, 2016, to comment on the draft guidance, the supporting document, or the risk assessment report. In early July 2016, the Federal eRulemaking Portal, *http://www.regulations.gov,* is undergoing maintenance. We are, therefore, extending the comment period for the draft guidance, the supporting document, and the risk assessment report. The extended comment period will close on July 19, 2016.

Dated: June 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15478 Filed 6–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0321]

Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice entitled "Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments" that appeared in the **Federal Register** of March 4, 2016. The notice requested scientific data, information, and comments that would assist in the development of a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure). In the **Federal Register** notice of April 22, 2016, the comment period for this request was initially extended to July 5, 2016. We are taking this action due to maintenance on the Federal eRulemaking portal in early July 2016.

DATES: FDA is extending the comment period on the notice published March 4, 2016 (81 FR 11572). Submit either electronic or written comments by July 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–0321 for "Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Campus Dr., College Park, MD 20740, 240–402–2927.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 22, 2016 (81 FR 23733), FDA published a notice giving interested persons until July 5, 2016, to comment on our request for scientific data, information, and comments that would assist us in our plan to develop a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure).

In early July 2016, the Federal eRulemaking Portal, *http://www.regulations.gov,* is undergoing maintenance. We are, therefore, extending the comment period for our request for scientific data, information, and comments. The extended comment period will close on July 19, 2016.

Dated: June 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15480 Filed 6–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Administration for Children and Families

Delegation of Authority

AGENCY: Office of the Secretary, Administration for Children and Families, HHS.

ACTION: Delegation of authority.

SUMMARY: Notice is hereby given that I delegate to the Assistant Secretary for the Administration for Children and Families (ACF) the following authorities vested in the Secretary of Health and Human Services under the Trafficking Victims Protection Act of 2000 (TVPA), Public Law 106–386, as amended.

Authority under section 107(b)(1)(B)(i) of the TVPA (22 U.S.C. 7105(b)(1)(B)(i)) to expand benefits and services to victims of severe forms of trafficking in persons in the United States, without regard to immigration status. In the case of non-entitlement programs funded by the Secretary of Health and Human Services, such benefits and services may include services to assist potential victims of trafficking in achieving certification and to assist minor dependent children of victims of severe forms of trafficking in persons or potential victims of trafficking.

Authority under section 107(b)(1)(B)(ii) of the TVPA (22 U.S.C. 7105(b)(1)(B)(ii)) to make grants for a national communication system to assist victims of severe forms of trafficking in persons in communicating with service providers.

Authority under section 107(f) of the TVPA (22 U.S.C. 7105(f)) to establish a program to assist United States citizens and aliens lawfully admitted for permanent residence who are victims of severe forms of trafficking. In addition to the authority to provide such victims with specialized services, the program also has the authority to identify current providers and provide a means to make referrals to programs for which such victims are already eligible. In the course of exercising the authority to conduct activities, personnel in the Administration for Children and Families will consult with the Attorney General, the Secretary of Labor, and non-governmental organizations that provide services to victims of severe forms of trafficking in the United States.

These authorities may be redelegated.

These authorities shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations.

These delegations shall be exercised under financial and administrative requirements applicable to the Administration for Children and Families authorities.

I hereby affirm and ratify any actions taken by the Assistant Secretary for Children and Families, or your subordinates, which involved the exercise of these authorities delegated herein prior to the effective date of this delegation.

This delegation supersedes all existing delegations of these authorities.

DATES: This delegation is effective upon signature.

Dated: June 21, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–15470 Filed 6–29–16; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: HHS approval of entities that certify Medical Review Officers (MRO).

SUMMARY: The current version of the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2010, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs.

DATES: HHS approval is effective June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Fan, Pharm.D., J.D., Division of Workplace Programs (DWP), Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), 5600 Fishers Lane, Room 16N02B, Rockville, MD 20857; Telephone: (240) 276–1759; Email: *jennifer.fan@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: Subpart M-Medical Review Officer (MRO), section 13.1(b) of the Mandatory Guidelines, "Who may serve as an MRO?" states as follows: "Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug testing results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall publish a list in the **Federal Register** of those entities and boards that have been approved."

HHS has completed its review of entities that certify MROs, in accordance with requests submitted by such entities to HHS.

The HHS Secretary approves the following MRO certifying entities that offer MRO certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709, Phone: (800) 489–1839, Fax: (919) 490–1010, Email: *cferrell@aamro.com*, Web site: *http://www.aamro.com/*.

Medical Review Officer Certification Council (MROCC), 836 Arlington Heights Road, #327, Elk Grove Village, IL 60007, Phone: (847) 631–0599, Fax: (847) 483–1282, Email: *mrocc@mrocc.org*, Web site: *http://www.mrocc.org/*.

Dated: June 22, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–15469 Filed 6–29–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the NIH Clinical Center Research Hospital Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The portions of the meeting devoted to the identification and evaluation of specific candidates for consideration for leadership positions in the Clinical Center will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B) and 552b(c)(6), Title 5 U.S.C., as amended. Premature disclosure of potential candidates and their qualifications, as well as the discussions by the committee, could significantly frustrate NIH's ability to recruit these individuals and the consideration of personnel qualifications, performance, and the competence of individuals as candidates would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Clinical Center Research Hospital Board.

Date: July 15, 2016.

Open: 8:30 a.m. to 3:00 p.m.

Agenda: Welcome and NIH Director's Overview, Clinical Center Leadership Feedback, Governance Structure, and Chief Executive Officer Characteristics.

Place: Conference Room 6C6, Building 31C, National Institutes of Health, Bethesda, MD 20892.

Closed: 3:15 p.m. to 5:00 p.m.

Agenda: Identification of Candidates for Leadership Roles.

Place: Conference Room 6C6, Building 31C, National Institutes of Health, Bethesda, MD 20892.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: June 24, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15446 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Drug Discovery and Mechanisms of Antimicrobial Resistance.

Date: July 28–29, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Guangyong Ji, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–1146, *jig@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cell Biology, Signaling, and Development.

Date: July 28, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Thomas Beres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr. Rm. 5201, MSC 7840, Bethesda, MD 20892, 301–435–1175, *berestm@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Interdisciplinary Molecular Sciences.

Date: July 28, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, Bethesda, MD 20892, 301–435–1047, *kkrishna@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 24, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15445 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Long Acting Therapeutic Conjugates With Evans Blue

This invention is a platform technology that pertains to the advantages of conjugating therapeutics to Evans Blue thus providing long lasting pharmacokinetic profiles by complexing with albumin. Notably, albumin bound therapeutic- or prodrug-Evans Blue conjugates provide a complex with a total molecular size above 60 kDa thus eliminating the risk for renal clearance. Interestingly, since albumin also crosses the blood-brain barrier and since all circulating Evans Blue is bound to albumin, Evans Blue bound therapeutics or prodrugs can also cross the blood-brain barrier. By way for example but not limitation, Evans Blue can be conjugated to insulin, GLP-1, exendin-4, exendin (9-39), octreotide, bombesin, RGD peptide (arginylglycylaspartic acid), vascular endothelial growth factor (VEGF), interferon (IFN), tumor necrosis factor (TNF), asparaginase, or adenosine deaminase, exenatide, dipeptidyl peptidase-4 inhibitors, neuropilin, epidermal growth factor, islet neogenesis associated protein, alpha-1 antitrypsin, anti-inflammatory agents, glulisine, glucagons, local cytokines, modulators of cytokines, anti-apoptotic molecules, aptamers, asparaginase, adenosine deaminase, interferon α2a, interferon α2b, granulocyte colony stimulating factor, growth hormone receptor antagonists, doxorubicin, paclitaxel, gemcitabine, camptothecin, and temozolomide. Evans Blue conjugates according to this invention can additionally include radionuclides like ^{18}F, ^{76}Br, ^{124}I, ^{125}I, or ^{131}I, or ^{117m}Sn for tracking or use in diagnostics.

Potential Commercial Applications:

—Diabetes therapeutics
—Cancer therapeutics
—CNS therapeutics
—Pharmacokinetic/distribution studies

Competitive Advantages:

—long pharmacokinetic profile
—no renal clearance of circulating drug

Development Stage:

- Early stage

Inventors: Xiaoyuan Chen, Lixin Lang, Gang NIU (all of NIBIB).

Intellectual Property: HHS Reference No. E–143–2015/0; U.S. Provisional Patent Application 62/182,694 filed June 22, 2015; International Patent Application PCT/US2016/38475 filed June 21, 2016.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Dated: June 23, 2016.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2016–15442 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used for Identifying Potential Developmental Toxicants

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for identifying potential developmental toxicants. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring.

DATES: *Receipt of information:* Deadline is August 15, 2016.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (919) 316–4729.

SUPPLEMENTARY INFORMATION:

Background: NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, is supporting efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants. The goal of these alternative approaches is to replace, reduce, or refine the use of animals in testing. Testing a chemical's potential to cause developmental toxicity is required by multiple regulatory agencies and may require the use of large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to identify potential developmental toxicants. Respondents should provide information on any activities relevant to the development or validation of alternatives to *in vivo* developmental toxicity test methods currently required by regulatory agencies, including data from non-animal chemical tests for developmental hazard potential. NICEATM also requests any available data resulting from *in vivo* developmental studies, ethical human or animal studies, or accidental human exposures, using the same chemicals.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is August 15, 2016. Responses to this notice will be posted at: *http://ntp.niehs.nih.gov/go/dev-nonanimal.* Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM in the development of alternative test methods. Information about NICEATM and ICCVAM is found at *http://ntp.niehs.nih.gov/go/niceatm* and *http://ntp.niehs.nih.gov/go/iccvam.*

Dated: June 24, 2016.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2016–15444 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel.

Date: July 27, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institutes of Health, NIAID, 5601 Fishers Lane MSC 9823, Bethesda, MD 20892–9823, (240) 669–5060, *james.snyder@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 24, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15443 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Multi-Photon Microscopy System Configured for Multiview Non-Linear Optical Imaging

This invention is a microscopy device and system for multi-photon microscopy utilizing multi-view nonlinear optical imaging. Nonlinear optical imaging remains the premier technique for deep-tissue imaging in which typically a multi photon arrangement may be used to illuminate and excite a sample. However, the penetration depth, signal-to-noise ratio, and resolution of this technique is ultimately limited by scattering. The present system addresses these issues by sequential excitation of a sample through three or more objective lenses oriented at different axes intersecting the sample. Each objective lens is capable of focused sequential excitation that elicits fluorescence emissions from the excited sample, which is then simultaneously detected by each respective objective lens along a respective longitudinal axis. Including multiple lenses will improve the penetration depth and at the same time decrease the loss of detail because of scattering. The system also can overcome losses in spatial resolution because of the scattering of the excitation and emission light.

Potential Commercial Applications:
- —High resolution multi-photon microscopy
- —Deep tissue visualization

—*Competitive Advantages:*
- —Improved signal-to-noise ratio
- —improved spatial resolution

—*Development Stage:*
- Prototype

Inventors: Yicong Wu (NIBIB), Hari Shroff (NIBIB), Jianyong Tang (NIAID), Ronald Germain (NIAID).

Intellectual Property: HHS Reference No. E–229–2015/0; U.S. Provisional Patent Application 62/210,153 filed August 26, 2015.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Dated: June 24, 2016.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2016–15441 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Member Conflict SEP.

Date: July 6, 2016.

Time: 10:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W602, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Delia Tang, MD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Rockville, MD 20850 240–276–7684, *tangd@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 24, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15447 Filed 6–29–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS

ACTION: Notice

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N03A, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center—Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.;

MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370, (Formerly: SmithKline Beecham Clinical Laboratories)

Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Summer King,

Statistician.

[FR Doc. 2016–15523 Filed 6–29–16; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167A2100DD/AAKC001030/A0A501010.99990 253G]

Proclaiming Certain Lands as Reservation for the Port Gamble S'Klallam Tribe of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice informs the public that the Acting Assistant Secretary—Indian Affairs proclaimed approximately 410.50 acres, more or less, an addition to the Reservation of the Port Gamble S'Klallam Tribe of Washington on June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene M. Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1849 C Street NW., MS–4642–MIB, Washington, DC 20240; telephone: (202) 208–3615.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according to the Act of June 18, 1934, (48 Stat. 984; 25 U.S.C. 467) for the land described below. The land was proclaimed to be part of the Port Gamble S'Klallam Indian Reservation of the Port Gamble S'Klallam Tribe in Kitsap County, Washington.

Port Gamble S'Klallam Indian Reservation

DNR Parcel

Legal Description Containing 390.26 Acres, More or Less

PARCEL A (Hansville Property North)—The North half of the Northeast quarter and North half of the Southwest quarter of the Northeast quarter, Section 16, Township 27 North, Range 2 East, W.M., Kitsap County, Washington, according to U.S. Government subdivision procedures, shown as Parcel A (North) on that survey recorded October 12, 2004 in Book 62 of Surveys at Pages 63 and 64, under Auditor's File Number 200410120005.

PARCEL B (Hansville Property South)—The South half of the Southwest quarter of the Northeast quarter, the South half of the Northeast quarter of the Southwest quarter; the Northwest quarter of the Southeast quarter; the Southeast quarter of the Southeast quarter; and the Northeast quarter of the Southeast quarter; except the east 495 feet of said Northeast quarter of the Southeast quarter of Section 16, Township 27 North, Range 2 East, W.M., Kitsap County, Washington, according to U.S. Government subdivision procedures, shown as Parcel B (South) on that survey recorded October 12, 2004, in Book 62 of Surveys at Pages 63 and 64, under Auditor's File Number 200410120005; Also excepting therefrom the West 26 feet of the East 521 feet of said Northeast quarter of the Southeast quarter of said Section 16.

PARCEL C (Hansville Property West)—East half of the Northwest quarter; the Southwest quarter of the Northwest quarter; the North half of the Northeast quarter of the Southwest quarter Section 16, Township 27 North, Range 2 East, W.M., Kitsap County, Washington; according to U.S. Government subdivision procedures, shown as Parcel C (West) on that survey recorded October 12, 2004, in Book 62 of Surveys at Pages 63 and 64, under Auditor's File No. 200410120005.

Pope Parcel

Legal Description Containing 20.24 Acres, More or Less

Lot(s) 1, Record of Survey, recorded in Volume 78, page(s) 23 and 24, of surveys, under Auditor's File No. 201308190235, being a portion of the Southeast Quarter, Section 9, Township 27 North, Range 2 East, W.M. in Kitsap County, Washington.

The above described lands contain a total of 410.50 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the lands described above, nor does it affect any valid existing easements for public roads, highway, public utilities, railroads, and pipelines or any other valid easements or rights-of-way or reservations of record.

Dated: June 22, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–15430 Filed 6–29–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167A2100DD/AAKC001030/A0A501010.999900]

Hannahville Indian Community Liquor Control Code

AGENCY: Bureau of Indian Affairs.

ACTION: Notice.

SUMMARY: This notice publishes the amended Hannahville Indian Community Liquor Control Code, title IV, chapter 13. The amended Code regulates and controls the possession, sale, and consumption of liquor in conformity with the laws of the Hannahville Indian Community or applicable laws of the State of Michigan.

DATES: This amendment is effective August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Sherrel LaPointe, Tribal Operations Officer, Midwest Region, Bureau of Indian Affairs, Norman Pointe II, 5600 American Boulevard West, Suite 500, Bloomington, Minnesota 55437, Telephone: (612) 713–4400.

SUPPLEMENTARY INFORMATION: The Hannahville Indian Community duly adopted the amended Code by Resolution Number 0504–2015–A on May 4, 2015. This Code repeals and replaces the previous liquor control code for the Hannahville Indian Community Liquor Control Code, last published in the **Federal Register** on April 14, 1976 (41 FR 15720).

Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor ordinances for the purpose of regulating liquor transactions in Indian country. This notice is published with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs. I certify that the Hannahville Indian Community duly adopted this amendment to the Hannahville Liquor Control Code by Resolution No. 0504–2015–A on May 4, 2015.

Dated: June 22, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

The Hannahville Indian Community Liquor Control Code, as amended, shall read as follows:

HANNAHVILLE INDIAN COMMUNITY LIQUOR CONTROL CODE

TITLE IV—CHAPTER 13

13.100 Short Title. This Code shall be known and may be cited as "The Hannahville Indian Community Liquor Control Code," or "The Liquor Control Code."

13.101 Definitions, General.

(1) "Alcohol"—the product of distillation of fermented liquid, whether or not rectified or diluted with water, but does not mean ethyl or industrial alcohol, diluted or not, that has been denatured or otherwise rendered unfit for beverage purposes.

(2) "Alcoholic Liquor"—any spirituous, vinous, or fermented liquor, liquids and compounds, whether or not medicated, proprietary, patented, and by whatever name called, containing ½ of 1% or more of alcohol by volume which are fit for use for beverage purposes as defined and classified by the commission according to alcoholic content as belonging to one of the varieties defined in this chapter.

(3) "Beer"—any beverage obtained by alcoholic fermentation of an infusion of decoction of barley, malt, hops or other cereal in potable water.

(4) "Brandy"—an alcoholic liquor as defined in 27 CFR 5.22(d) (1980).

(5) "Class C License"—a place licensed to sell at retail beer, wine, mixed spirit drink, and spirits for consumption on the premises.

(6) "Community"—the Hannahville Indian Community.

(7) "Council"—the Tribal Council of the Hannahville Indian Community.

(8) "Licensee"—Any entity or person licensed to sell beverages containing alcohol in accordance with the laws of the Hannahville Indian Community or applicable laws of the State of Michigan. Except where otherwise specifically required by applicable law or regulation, use of the word licensee shall be understood to include the word permittee.

(9) "Mixed Spirit Drink"—a drink produced and packaged or sold by a mixed spirit drink manufacturer or an out of state seller of mixed spirit drink, which contains 10% or less alcohol by volume consisting of distilled spirits mixed with nonalcoholic beverages or flavoring or coloring materials and which may also contain water, fruit juices, fruit adjuncts, sugar, carbon dioxide or preservatives.

(10) "Mixed Wine Drink"—a drink or similar product marketed as a wine cooler and containing less than 7% alcohol by volume, consisting of wine and plain, sparkling or carbonated water and containing 1 or more of the following:

(a) Nonalcoholic Beverages.
(b) Flavoring.
(c) Coloring Materials.
(d) Fruit Juices.
(e) Fruit Adjuncts.
(f) Sugar.
(g) Carbon Dioxide.
(h) Preservative.

(11) "Permittee"—Any entity or person licensed to sell beverages containing alcohol in accordance with the law or regulation of the Hannahville Indian Community or applicable laws or regulations of the State of Michigan. Except where otherwise specifically required by applicable law or regulation, use of the word licensee shall be understood to include the word permittee.

(12) "Sacramental Wine"—wine containing not more than 24% of alcohol by volume which is used for sacramental purposes.

(13) "Seller"—a person who has become at least 18 years of age and who is authorized by a licensee or permittee to sell beverages containing alcohol while acting within the scope of the license or permit that has been issued by the Tribe.

(14) "Spirits"—a beverage that contains alcohol obtained by distillation, mixed with potable water or

other substances, or both, in solution, and includes wine containing an alcoholic content of more than 21% by volume, except sacramental wine and mixed spirit drink.

(15) "Tribe"—the Hannahville Indian Community.

(16) "Wine"—the product made by the normal alcoholic fermentation of the juice of sound, ripe grapes or any other fruit with the usual cellar treatment, and containing not more than 21% alcohol by volume, including fermented fruit juices other than grapes and mixed wine drinks.

13.102 General Prohibition.

It shall be unlawful to manufacture for sale, sell, offer, serve, trade, or keep for sale, possess, transport or conduct any transaction involving any alcoholic beverage except in compliance with the terms, conditions, limitations and restrictions specified in this Code.

13.103 Tribal Council; Control of Alcoholic Beverages.

(1) The Tribal Council shall have the sole and exclusive right to authorize, permit, license and control the importation, sale, possession, manufacture, transportation, storage or delivery of alcoholic beverages within the jurisdiction of the Hannahville Indian Community.

(2) Notwithstanding the provision of subsection (1) of this section, a person who has become 21 years of age may purchase alcoholic liquor or may import alcoholic liquor from another jurisdiction for that person's personal use, but not for resale purposes.

13.104 Penalty; Failure to Comply.

Any person who shall sell, serve, trade, transport, keep for sale, manufacture, possess, use, conduct any transaction, aid or abet or conspire to violate any of the terms of this Code within the jurisdiction of the Hannahville Indian Community shall be deemed guilty of an offense and upon conviction shall be dealt with as follows:

(1) If an Indian. The defendant may be sentenced to a period of incarceration not to exceed 1 year or a fine not to exceed $5,000.00, or both such fine and incarceration and court costs. The Tribal Council shall decide whether or not any license previously granted under this Code will be revoked or suspended.

(2) If a Non-Indian. Unless otherwise allowed by law, the defendant shall be liable for a fine not to exceed $5,000.00 and court costs, and shall be subject to the forfeiture and attachment laws of the tribe including prejudgment attachment of personal property in lieu of cash bond to secure judgment and jurisdiction of the tribal court. In the event that criminal jurisdiction as to non-Indians is extended to the Tribe as a matter of federal law then the penalties of section 13.104(1) shall apply. The Tribal Council shall decide whether or not any license previously granted under this Code will be revoked or suspended.

(3) No Pre-Emption. This Code does not pre-empt other civil or criminal codes or provisions of the Hannahville Indian Community Legal Code. Other causes of action and criminal charges that may be brought under other provisions of tribal law are expressly reserved hereunder. Actions required or permitted to be taken pursuant to the employment policies and procedures of the Tribe are also expressly reserved.

13.105 Licensees and Permittees: Ages of Sellers and Purchasers; Types of Licenses; Sale to Obviously Intoxicated Persons; Adulterated Alcoholic Beverages Prohibited; Licensee's and Permittee's Liability for Acts of Sellers.

(1) Age of Sellers. Sellers of alcoholic beverages must be at least 18 years of age and are only permitted to make sales of beverages containing alcohol by express authorization within the scope of a licensee's or permittee's license or permit and on authorized business premises.

(2) Age of Purchasers. Purchasers of alcoholic beverages must be at least 21 years of age and shall show proper identification and proof of age upon purchase.

(3) Licenses or Permits; Hours of Sale. Hours of sale of alcoholic beverages will be determined upon issuance of the license or special permit, and will be in conformity with the type of license or permit authorized by the Tribal Council in conformity to applicable substantive state law.

(a) Special Event Permits; Conformity to Tribal and Applicable State Law. Permits issued by the Hannahville Indian Community under this Code to any person or entity for special events shall be issued in conformity with applicable substantive provisions of Michigan law or regulation as to times of sales and service, ages of purchasers, and duration of events.

(4) Sales to Obviously Intoxicated Persons. No person may sell, serve, give, furnish, or in any way procure for another, alcoholic beverages for the use of an obviously intoxicated person.

(5) Consumption of Alcohol by Obviously Intoxicated Persons On Premises Prohibited. A licensee or permittee shall not allow a person who is in an obviously intoxicated condition to consume beverages containing alcohol on the licensed or permitted premises.

(6) Adulterated Alcoholic Beverages; Regulation. No person may sell, serve, give, furnish or in any way procure for another any diluted or adulterated alcoholic beverage except as allowed by special license providing for the sale of mixed drinks on the premises of the licensee.

13.106 Licensees and Permittees; Liability for Acts of Sellers or Servers.

Every licensee or permittee is responsible for the conduct of sellers or servers authorized to participate in transactions related to alcoholic beverages on the premises of the licensee. Provided, however, that if the licensee is a tribally wholly owned enterprise this provision does not constitute a waiver of tribal sovereign immunity as to the enterprise nor as to the Tribe.

13.107 Licensees and Permittees; Who or What Entity May Apply; Standard for Approval.

Any person who has become 21 years of age, including a tribally owned business entity may apply for an alcoholic beverage license or special permit by submitting an application containing the information required in 13.109, and may be granted a license or special permit for the sale, service, use, possession or transport of alcoholic beverages if the Tribal Council finds, in its sound discretion, on the basis of the facts disclosed by the application and by such additional information as the Council may deem relevant, that such issuance is in the best interest of the Community. Factors which the Tribal Council shall consider in granting, renewing or revoking a license shall include, but not be limited to, information required by section 13.109. Special licenses or permits may be granted to tribal organizations for special events, charitable functions, and special tribal celebrations.

13.108 Licenses; Power to License and Tax.

The power to license or permit and to levy taxes under the provisions of this Code is vested exclusively in the Tribal Council.

13.109 Licenses and Permits: Application; Term of Licenses.

(1) Applications; Content. An applicant for a license or permit shall provide in the application or demonstrate at a hearing all of the following:

(a) Name. The name of the person or entity seeking a license or permit.

(b) Financial Resources. The existence of adequate financial resources for establishment and operation of the proposed licensed business in proportion to the type and size of the proposed licensed business.

(c) Physical Plant. The existence of an adequate physical plant or plans for an adequate physical plant appropriate for the type and size of the proposed licensed business.

(d) Location. That the location of the proposed business shall adequately service the public.

(e) Permit; Nature of Event. In the case of a permit, a description of the nature of the event and the premises upon which, or within which the event is to occur.

(2) Competing Applications. The Council shall consider the order in which competing application forms are submitted to the Council.

(3) License Renewal; Term of License. Licenses are renewable by action of each new Tribal Council on the anniversary date which occurs at one year from last issuance. Licenses may be granted for any term less than one year but may not be granted for terms of more than three years.

(4) Permits; Term of Permit. Generally, a permit will be granted by the Tribe pursuant to this Code and in accordance with applicable state law or regulation for special events and will be limited to the length of time that the event is to occur.

(5) Notice and Opportunity to be Heard. The Council shall notify the applicant of its decision giving the reason(s) for its decision. In adverse determinations, and upon timely request, which shall occur not more than 5 business days after notice of the adverse action, the Tribal Council shall provide a hearing to the applicant. There is no appeal from the Council's decision.

13.110 Licenses and Permits; Content; Posting; Non-Transferable.

(1) Licenses and Permits; Content. Each license or permit shall state the name of the license holder and address of the place of business to which it applies; the date of issuance; the date of expiration; the fact that the license or permit is granted by the Hannahville Indian Community Tribal Council; a statement, with the telephone number of the Hannahville Tribal Police Department that violations of the terms of the license or permit or the Liquor Control Code of the Hannahville Indian Community shall be reported to the Hannahville Indian Community Tribal Police who shall report their findings to the Tribal Council.

(2) Posting of Licenses and Permits. Licenses and permits shall be posted in a conspicuous place on the premises of the license holder.

(3) Licenses and Permits; Non-Transferable. Licenses and permits are not transferable to other persons, locations or business entities.

13.111 Licensee, Permittee, Liability Policy; Proof of Financial Responsibility.

Every licensee or permittee shall have proof of liability insurance or bond as required by applicable state law or regulation.

13.112 Licenses; Violation Report; Complaint; Notice of Hearing; Revocation; No Appeal.

(1) Violation; Investigation; Procedure. Upon receiving notice of a violation of this Code, the Hannahville Indian Community Tribal Police shall investigate and submit a report to the Tribal Council.

(2) License or Permit; Suspension; Revocation. The Tribal Council may choose to act immediately in response to the alleged violation by suspension or revocation of the license or permit, or may act at any time during or after a prosecution on the complaint. The Council may take any appropriate action in relation to the license, including suspension or revocation and may assess fines civilly against persons responsible for the violation in accord with section 13.104(1) or (2). Such fines may be in addition to any fines, damages or court costs that are assessed pursuant to other provisions of law. The Council may in its deliberations consider any evidence which it considers valuable and relevant.

(3) Notice and Opportunity to be Heard. The Council shall notify the licensee or permittee of its action giving the reason(s) for its decision. Upon timely request, which shall occur not more than 5 business days after notice of the adverse action, the Tribal Council shall provide a hearing to the licensee or permittee. In its discretion, and upon consultation with law enforcement and legal counsel, the Tribal Council may delay a hearing to allow for progress of a court action. There is no appeal from the Council's decision in regard to continued licensure or permitting.

(4) Any appeal from a court action shall be limited to the issues presented and preserved for appeal in the court below.

13.113 Licenses; Hours of Sale; Sunday and Christmas Holiday Liquor Transactions.

In addition to compliance with the requirements of section 13.105, class III gaming and other properly licensed tribally owned establishments may sell at retail, and a person may buy, spirits or mixed spirit drinks, including beer and wine or other beverages containing alcohol between the hours of 7:00 a.m. on Sunday and 2:00 a.m. on Monday unless shorter hours of sale have been specified by the Tribal Council pursuant to special license or permit. A person shall not sell at retail, and a person shall not knowingly and willfully buy, alcohol, or liquor of any kind between the hours of 11:59 p.m. on December 24 and 12 noon on December 25.

(1) Violation of Hours of Sale. It shall be a violation of this section, punishable in accordance with section 13.104, for a person to attempt to, or to sell, serve, furnish, purchase, or to procure for another, alcoholic beverages in violation of the hours of sale allowed by this Code.

(2) Time Zones; Clarification. In accordance with Michigan law, times for allowed sales shall be considered to be CST, for any licensee or permittee located in the central time zone. A reference to the time of day includes daylight savings time, when observed.

(3) Amendment Automatic, Substantive State Law. Amendments to this Code to achieve compliance with applicable substantive state law shall occur automatically as Michigan law is further amended.

(4) Notice of Automatic Amendment. If automatic amendment of this Code in accordance with applicable substantive state law occurs, the Tribal Council shall notify all current licensees, permittees, law enforcement, and the general public, of the substance of such amendments in a manner calculated to give actual and adequate notice of the amendments and their effective dates.

13.114 The Tribe as Purchaser.

(1) Class III Gaming Facility; Purchase and Resale of Alcohol. The Tribe, for resale at its Class III gaming establishment, shall purchase spirits, or mixed spirit drinks, including beer and wine or other alcoholic liquor from distributors licensed or otherwise authorized by the Michigan Liquor Control Commission, at the same price and on the same basis that such beverages are purchased by class C licensees.

(2) Convenience Store; Other Enterprises. The Tribe, for resale at its Island Oasis convenience store and gas

station, or other properly licensed tribally owned facilities, may purchase spirits, or mixed spirit drinks, including beer and wine or other alcoholic liquor in accordance with tribal law and applicable state and federal law.

13.115 Adulterated and Misbranded Liquors and Refilled Liquor Bottles; Penalty, Definitions.

(1) "Adulterated, Misbranded Liquor; Violation." A licensee who, by himself or herself or by his or her agent or employee, sells, offers for sale, exposes for sale, or possesses alcoholic liquor that is adulterated, misbranded, or in bottles that have been refilled is guilty of a violation of this act.

(2) "Adulterated Liquor; Definition." For purposes of this section, alcoholic liquor is adulterated if it contains any liquid or other ingredient that was not placed there by the original manufacturer or bottler.

(3) "Misbranded Liquor, Definition." For purposes of this section, alcoholic liquor is misbranded if it is not plainly labeled, marked, or otherwise designated.

(4) "Refilled Liquor Bottles." For purposes of this section, alcoholic liquor bottles have been refilled when the bottles contain any liquid or other ingredient not placed in the bottles by the original manufacturer or bottler.

(5) "Beer; Inapplicability." This section does not apply to beer containers.

13.116 Amendment or Repeal of Code.

This Code may be amended or repealed by a majority vote of the Tribal Council with a quorum present, in regular or special session.

13.117 Severability.

If any portion of this Code, or the application thereof, is found to be invalid the remainder shall be unaffected and shall remain in full force and effect.

[FR Doc. 2016–15428 Filed 6–29–16; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–21175; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before May 28, 2016, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by July 15, 2016.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before May 28, 2016. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

ALABAMA

Lawrence County

Wheeler Hydroelectric Project, (Tennessee Valley Authority Hydroelectric System, 1933–1979 MPS) 24455 AL 101, Rogersville, 16000431

Marshall County

Guntersville Hydroelectric Project, (Tennessee Valley Authority Hydroelectric System, 1933–1979 MPS) 3464 Snow Point Rd., Guntersville, 16000432

ARKANSAS

Bradley County

Warren Commercial Historic District, Roughly bounded by Alabama, Elm, Chestnut, 2nd, Church, Main & Howard Sts., Warren, 16000433

CALIFORNIA

Los Angeles County

View Park Historic District, Roughly bounded by Mt. Vernon, Enoro, Northland & Northridge Drs., Kenway, S. Victoria & Floresta Aves., Los Angeles, 16000434

DISTRICT OF COLUMBIA

District of Columbia

U.S. Post Office Department Mail Equipment Shops, 2135 5th St. NE., Washington, 16000435

MAINE

Cumberland County

Schlotterbeck and Foss Building, 117 Preble St., Portland, 16000436

Kennebec County

Seton, Elizabeth Ann, Hospital, 30 Chase Ave., Waterville, 16000437

Sagadahoc County

Huse, John E.L., Memorial School, 39 Andrews Rd., Bath, 16000438

Washington County

Eastport Historic District (Boundary Increase), 15 Sea St., Eastport, 16000439

MINNESOTA

Hennepin County

Lake Street Sash and Door Company, 4001–4041 Hiawatha Ave., Minneapolis, 16000440

Northstar Center, 625 Marquette Ave. & 608, 618 & 618 1/2 2nd Ave. S., Minneapolis, 16000441

NORTH DAKOTA

Williams County

Creaser Building, 224 Main St., Williston, 16000442

RHODE ISLAND

Providence County

Braitsch, William J. and Company, Plant, 472 Potters Ave., Providence, 16000443

SOUTH CAROLINA

Richland County

Carolina Life Insurance Company, 1501 Lady St., Columbia, 16000444

A request for removal has been received for the following resources:

COLORADO

Boulder County

Snowbound Mine, Co. Rd. 52, Gold Hill, 89000998

NORTH DAKOTA

Bottineau County

State Bank of Antler, Antler Sq., Antler, 88000986

Authority: 60.13 of 36 CFR part 60.

Dated: May 31, 2016.

Julie Ernstein,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2016–15086 Filed 6–29–16; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–16–023]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: July 8, 2016 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701–TA–562 and 731–TA–1329 (Preliminary) (Ammonium Sulfate from China). The Commission is currently scheduled to complete and file its determination on July 11, 2016; views of the Commission are currently scheduled to be completed and filed on July 18, 2016.
5. Vote in Inv. Nos. 731–TA–770–773 and 775 (Third Review) (Stainless Steel Wire Rod from Italy, Japan, Korea, Spain, and Taiwan). The Commission is currently scheduled to complete and file its determinations and views of the Commission on July 25, 2016.
6. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: June 27, 2016.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2016–15633 Filed 6–28–16; 11:15 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0010]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection U.S. Official Order Forms for Schedules I and II Controlled Substances DEA Form 222

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 29, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Courtney E. Mallon, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* U.S. Official Order Forms for Schedules I and II Controlled Substances.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form: 222. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act (CSA) (21 U.S.C. 801–971) establishes a closed system of distribution for controlled substances. To this end, controlled substances are closely monitored and tightly regulated as they are distributed through the supply chain. One tool that helps to maintain the closed system of distribution is the CSA provision that states it "shall be unlawful for any person to distribute a controlled substance in schedules I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section.." 21 U.S.C. 828(a).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 125,435 registrants participate in this information collection, taking an estimated 11.6 hours per registrant annually.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates the total public burden (in hours) associated with this collection: 1,453,348 annual burden hours.

If additional information is required please contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3E.405B, Washington, DC 20530.

Dated: June 27, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–15492 Filed 6–29–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0018]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; OSC Charge Form

AGENCY: Civil Rights Division, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Civil Rights Division, Office of Special Counsel for Immigration-Related Unfair Employment Practices, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 81 FR 24129, on April 25, 2016, allowing for a 60-day comment period.

DATES: The purpose of this notice is to allow for an additional 30 days for public comment until August 1, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Alberto Ruisanchez, Deputy Special Counsel, USDOJ–CRT–OSC, 950 Pennsylvania Avenue NW–NYA, Washington, DC 20530. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

Written comments and/or suggestions are requested from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, mechanical, or other technological collection techniques or other forms of information technology.

The information collection is listed below:

(1) Type of information collection: Extension of Currently Approved Collection.

(2) The title of the form/collection: Office of Special Counsel for Immigration-Related Unfair Employment Practices Charge Form [OSC Charge Form].

(3) The agency form number and applicable component of the Department sponsoring the collection. Form OSC–1. Office of Special Counsel for Immigration-Related Unfair Employment Practices, Civil Rights Division, U.S. Department of Justice.

(4) Affected public who will be asked to respond, as well as a brief abstract: Primary: The Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) enforces the anti-discrimination provision (§ 274B) of the Immigration and Nationality Act (INA), 8 U.S.C. 1324b. The statute prohibits: (1) Citizenship or immigration status discrimination in hiring, firing, or recruitment or referral for a fee, (2) national origin discrimination in hiring, firing, or recruitment or referral for a fee, (3) unfair documentary practices during the employment eligibility verification (Form I–9 and E-Verify) process, and (4) retaliation or intimidation for asserting rights covered by the statute. OSC, within the Department's Civil Rights Division, investigates and, where reasonable cause is found, litigates charges alleging discrimination. OSC also initiates independent investigations, at times based on information developed during individual charge investigations. Independent investigations normally involve alleged discriminatory policies that potentially affect many employees or applicants. These investigations may result in complaints alleging a pattern or practice of discriminatory activity. If the Department lacks jurisdiction over a particular charge but believes another agency with which OSC has a Memorandum of Understanding providing for cross referrals (OSC has over fifty MOU partners) has jurisdiction over the claim, the completed form will be forwarded to the appropriate agency, thus avoiding any duplicative requests for information. OSC will also refer Respondents to non-MOU partner agencies where appropriate.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 210 respondents per year at 30 minutes per charge form.

(6) An estimate of the total public burden (in hours) associated with the collection: 105 hours annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Two Constitution Square, 145 N Street NE., Room 3E.405B, Washington, DC 20530.

Dated: June 27, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–15490 Filed 6–29–16; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0184]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of currently approved collection: 2017 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 29, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rachel Morgan, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW., Washington, DC 20531 (email: *Rachel.Morgan@usdoj.gov;* telephone: 202–616–1707).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of currently approved collection.

(2) *The Title of the Form/Collection:* School Crime Supplement to the National Crime Victimization Survey.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number for the questionnaire is SCS–1. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The survey will be administered to persons ages 12 to 18 in NCVS sampled households in the United States. The SCS collects, analyzes, publishes, and disseminates statistics on the students' victimization, perceptions of school environment, and safety at school.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

An estimate of the total number of respondents is 8,889 persons ages 12 to 18. Of the 8,889 SCS respondents, 86% or 7,645 will complete the long SCS interview (entire SCS questionnaire) which will take an estimated 15 minutes to complete. The remaining 14% or 1,244 SCS respondents will complete the short interview (*i.e.* will be screened out for not being in school), which will take an estimated 3 minutes to complete. Respondents will be asked to respond to this survey only once during the six month period. The burden estimates are based on data from the prior administration of the SCS.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,973 total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: June 27, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–15491 Filed 6–29–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Reopened Availability of Funds and Funding Opportunity Announcement for the Senior Community Service Employment Program (SCSEP) National Grants for Program Year (PY) 2016

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Funding Opportunity Announcement (FOA) re-opening.

Funding Opportunity Number: FOA–ETA–16–04–A.

SUMMARY: The Employment and Training Administration (ETA), U.S. Department of Labor (DOL, the Department, or we), announces a reopening of the availability of approximately $338,520,000 in grant funds authorized by title V of the Older Americans Act (OAA) as amended in 2006, Public Law 109–365 for the Community Service Employment for Older Americans program, commonly referred to as the Senior Community Service Employment Program (SCSEP), for National Grants for Program Year (PY) 2016.

DATES: The original **Federal Register** Notice, 81 FR 15745, was published on March 24, 2016. The closing date for receipt of applications under this announcement is July 25, 2016. Applications must be received no later than 4:00:00 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT: Jeannette Flowers, 200 Constitution Avenue NW., Room N–4716, Washington, DC 20210; Telephone: 202–693–3322.

SUPPLEMENTARY INFORMATION: ETA is reopening the SCSEP FOA open period for 30 days to both new applicants and to applicants who applied for funding under this FOA during the previous open period. This reopening is intended to ensure adequate coverage of the necessary geographic areas and associated participant slots. Details on how to apply for new applicants and for existing applicants which wish to submit a new application are available in the FOA as well as any subsequent amendments to the FOA, which are described in further detail on ETA's Web site at *https://www.doleta.gov/grants/find_grants.cfm* or on *http://www.grants.gov.* The Web sites provide application information, eligibility requirements, review and selection procedures, and other program requirements governing this funding opportunity. SCSEP is the only Federally-sponsored employment and training program targeted specifically to low-income older individuals who are able to enter or reenter the workforce. Program participants receive paid work experience at local public or non-profit agencies and are paid the higher of the Federal, State, or local minimum wage, or the prevailing wage for similar employment, for approximately 20 hours per week while in community service and other job training (OAA Amendments § 502(b)(1)(J); 20 CFR 641.565(a)). The dual goals of the program are to promote useful opportunities in community service job training and to move SCSEP participants into unsubsidized employment.

We anticipate awarding approximately 10–22 grants ranging from $2 million to $50 million each under this FOA. This is a four-year grant, renewable annually for each of those four years based on annual Departmental application requirements and subject to the availability of funds. The grant may be extended for a fifth year at the Department's discretion, contingent upon the grantee meeting or exceeding the minimum negotiated performance measures as required by section 514(a) of the OAA Amendments and 20 CFR 641.700.

Jimmie Curtis is the Grant Officer for the Funding Opportunity Announcement.

Signed June 23, 2016 in Washington, DC

Donna Kelly,

Grant Officer, Employment and Training Administration.

[FR Doc. 2016–15466 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Unemployment Insurance Benefits Operations State Self-Assessment Report of Responses

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, "Unemployment Insurance Benefits Operations State Self-Assessment Report of Responses." In 2014, ETA embarked on a major multi-year initiative to reengineer its program accountability processes for state unemployment insurance (UI) benefits operations by integrating peer reviews with new operational review processes that recognizes both Federal and state capacity and ensures that the UI program is administered with a focus on accountability and integrity. Recognizing the need to assess and adequately monitor state UI benefit program operations in the 53 jurisdictions with state UI programs, the ETA has developed a new comprehensive state self-assessment tool, which is a set of questionnaires related to state UI benefits operations. The new collection has two distinct and complimentary purposes: (1) Assisting state UI agencies in making improvements to their UI benefits operations; and (2) assisting ETA in oversight and monitoring of state UI benefit program operations.

This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*

DATES: Consideration will be given to all written comments received by August 29, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Betty Castillo, Chief of the Division of Unemployment Insurance Operations, by telephone at (202) 693–3029, (this is not a toll-free number), TTY 1–877–889–5627, or by email at *Castillo.Betty@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, ETA Office of Unemployment Insurance, FPB Room S–4524, 200 Constitution Ave. NW., Washington, DC 20210; by email: *Castillo.Betty@dol.gov;* or by Fax (202) 693–3229.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The self-assessment report contains responses to a series of in-depth questions on functional and program areas within state UI benefits operations. ETA has developed questionnaires for the following fifteen functional and program areas within UI benefit operations: (1) Adjudications/Benefits Timeliness and Quality Reviews; (2) Benefit Payment Control; (3) Continued Claims and Eligibility Reviews; (4) Data Validation; (5) Disaster Unemployment Assistance; (6) Intake Claims—Unemployment Compensation for Ex-Servicemembers; (7) Intake Claims—Unemployment Compensation for Federal Employees; (8) Intake Initial Claims—Combined Wage Claims; (9) Intake—Initial Claims; (10) Internal Security; (11) Lower Authority Appeals and Higher Authority Appeals; (12) Overarching Operational Matters; (13) Short-Time Compensation; (14) Trade Readjustment Allowances; and (15) Worker Profiling and Reemployment Services and Reemployment Services and Eligibility Assessments. Each functional or program area questionnaire of the self-assessment tool covers nine operational elements (where applicable for the specific functional or program area). The operational elements are: (1) Procedures, Policies and Confidentiality; (2) Training; (3) Workload Analysis and Management Controls; (4) Performance Management; (5) Information Technology; (6) Claimant and Employer Access and Communication; (7) Operational Efficiency and Resource Allocation; (8) Staffing and Merit Staffing; and (9) Fiscal Management. Instructions have also been developed describing the overall use of the tool as well as separate sets of instructions for each functional or program area questionnaire.

As previously noted, the new Unemployment Insurance Benefits Operations State Self-Assessment Report of Responses has two distinct and complimentary purposes: (1) Assisting state UI agencies in making improvements to their UI benefits operations; and (2) assisting ETA in oversight and monitoring state UI benefit program operations.

State Use: At the conclusion of the self-assessment review, the results should be shared with state UI Administrators and appropriate program managers. The state's practices in all functional or program areas should be reviewed thoroughly to identify issues which may be the cause of poor operational performance as well as areas where the state is performing well. If training needs are identified, appropriate training curriculum should be developed and delivered to staff. The functional and program area questions may also be used to identify policies and procedures that are outdated and which should be brought up-to-date and published for appropriate staff to use. Use of self-assessment data can help to create a culture that supports both positive and negative feedback in planning and managing change. Administrators should also use the review results as a means to confirm the state's proper use of merit staff, its management of administrative grant funds, its continuity of operations plans, and other related business practices that are essential to the state's benefits operations. The state agency leadership should also use the self-assessment review results to identify any successful or promising practices occurring in the state UI operations that can be shared with other states. Such identified practices can be shared on the UI Community of Practice operated by ETA.

ETA Use: The state self-assessment responses will support periodic reviews conducted by ETA staff, by which they assess the state's activities in relation to State and Federal laws and regulations, including the state's compliance with Federal requirements. The information gathered from the self-assessments will enable ETA Regional Office staff to work with the state to identify areas where performance improvements are needed. The results will be used to inform ETA's technical assistance efforts nationally and with individual states, and will enable a more robust and effective collection and dissemination of state best practices. Information on states' operational issues that will be gathered from the report of responses of the states' self-assessments, as well as information on the states' timeliness and quality performance measures, improper payment rates, and information from ETA Regional Office monitoring and/or technical assistance efforts, will be used by ETA in identifying "high priority" states. States that are deemed to be "high priority" will be subject to more intensive monitoring and technical assistance from ETA related to its benefits operations and the state will be required to address identified issues in a corrective action plan submitted as part of the State's Quality Service Plan.

Section 303(a)(6) of the Social Security Act, 42 U.S.C. 503(a)(6) authorizes this information collection.

This information collection is subject to the Paperwork Reduction Act (PRA). A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention the "Unemployment Insurance Benefits Operations State Self-Assessment Report of Responses."

Submitted comments will also be a matter of public record for this ICR and posted on the Internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–ETA.

Type of Review: "NEW".

Title of Collection: Unemployment Insurance Benefits Operations State Self-Assessment Report of Responses.

Form: Not Applicable.

OMB Control Number: XXXX–0NEW.

Affected Public: State Government.

Estimated Number of Respondents: 53.

Frequency: Annually.

Total Estimated Annual Responses: 53.

Estimated Average Time per Response: 2,080 hours.

Estimated Total Annual Burden Hours: 110,240 hours.

Total Estimated Annual Other Cost Burden: $8,902,982.20.

Portia Wu,

Assistant Secretary for Employment and Training, U.S. Department of Labor.

[FR Doc. 2016–15467 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for Form ETA 9033 Attestation by Employers Using Alien Crewmembers for Longshore Activities in U.S. Ports (OMB Control Number 1205–0309) and Form ETA 9033–A, Attestation by Employers Using Alien Crewmembers for Longshore Activities in the State of Alaska (OMB Control Number 1205–0309)

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL or Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. 3506(c)(2)(A)]. This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Employment and Training Administration (ETA) is soliciting comments concerning the collection of data about Form ETA 9033 *Attestation by Employers Using Alien Crewmembers for Longshore Activities in U.S. Ports* and Form ETA 9033A, *Attestation by Employers Using Alien Crewmembers for Longshore Activities in the State of Alaska* in OMB Control Number 1205–0309. The forms and information collections in this control number expire December 31, 2016. These forms are used by employers to request permission to use foreign crewmen at U.S. Ports for longshore work. A copy of the proposed information collection request can be obtained free of charge by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before August 29, 2016.

ADDRESSES: Submit written comments to Brian Pasternak, National Director of Temporary Programs, Office of Foreign Labor Certification, Employment & Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Suite 12–200, Washington, DC 20210; Telephone: (202) 513–7350 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD). Fax: 202–513–7495. Email: *ETA.OFLC.Forms@dol.gov* subject line: ETA–9033 and ETA–9033A. A copy of the proposed information collection request (ICR) can be obtained free of charge by contacting the office listed above.

SUPPLEMENTARY INFORMATION:

I. Background

The information collection is required by section 258 of the Immigration and Nationality Act (INA) (8 U.S.C. 1288) and 20 CFR 655 Subpart F. The INA generally prohibits the performance of longshore work by foreign crewmembers in U.S. ports. 8 U.S.C. 1288(a). However, the INA contains an exception to this general prohibition where the use of foreign crewmembers is permitted by an applicable collective bargaining agreement or otherwise is a prevailing practice at the U.S. port. 8 U.S.C. 1288(c)(1). Under the prevailing practice exception, before any employer may use foreign crewmembers to perform longshore activities in U.S. ports, it must submit an attestation to the Secretary of Labor containing the elements required by the INA. 8 U.S.C. 1288(c)(1)(B). The INA further requires that the Secretary of Labor make available for public examination in Washington, DC a list of employers that have filed attestations and for each of these employers, a copy of the employer's attestation, and accompanying documentation received by the Secretary. 8 U.S.C. 1288(c)(4). Similarly, the INA permits foreign crewmembers to perform longshore work in the State of Alaska if the employer complies with certain attestation requirements. 8 U.S.C. 1288(d).

The information is being collected to ensure compliance with the INA's requirements that employers must make certain attestations as a condition precedent to the employer's use of foreign crewmembers to perform longshore activities in the U.S. The attestations required by section 258 are collected by the Secretary of Labor through his or her designee, the Employment & Training Administration, on Form ETA 9033, *Attestation by Employers Using Alien Crewmembers for Longshore Activities in U.S. Ports* and Form ETA 9033A, *Attestation by Employers Using Alien Crewmembers for Longshore Activities in the State of Alaska* under OMB Control Number 1205–0309. The Department is not proposing any changes to the collection and is requesting a three year extension.

II. Review Focus

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions:

Type of Review: Extension Title: Form ETA 9033, *Attestation by Employers Using Alien Crewmembers for Longshore Activities in U.S. Ports* and Form ETA 9033A, *Attestation by Employers Using Alien Crewmembers for Longshore Activities in the State of Alaska.*

OMB Number: 1205–0309.

Affected Public: Business or other for-profits.

Form(s): ETA–9033 and ETA–9033A.

Total Annual Respondents: 7.

Annual Frequency: 1.

Total Annual Responses: 7.

Average Time per Response: 3 hours 15 minutes.

Estimated Total Annual Burden Hours: 23.

Total Annual Burden Cost for Respondents: $0.

Comments submitted in response to this comment request will be summarized and/or included in the request for OMB approval of the ICR; they will also become a matter of public record.

Portia Wu,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2016–15468 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the "The Consumer Expenditure Surveys: The Quarterly Interview and the Diary." A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before August 29, 2016.

ADDRESSES: Send comments to Nora Kincaid, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Nora Kincaid, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Consumer Expenditure (CE) Surveys collect data on consumer expenditures, demographic information, and related data needed by the Consumer Price Index (CPI) and other public and private data users. The continuing surveys provide a constant measurement of changes in consumer expenditure patterns for economic analysis and to obtain data for future CPI revisions. The CE Surveys have been ongoing since 1979.

The data from the CE Surveys are used (1) for CPI revisions, (2) to provide a continuous flow of data on income and expenditure patterns for use in economic analysis and policy formulation, and (3) to provide a flexible consumer survey vehicle that is available for use by other Federal Government agencies. Public and private users of price statistics, including Congress and the economic policymaking agencies of the Executive branch, rely on data collected in the CPI in their day-to-day activities. Hence, data users and policymakers widely accept the need to improve the process used for revising the CPI. If the CE Surveys were not conducted on a continuing basis, current information necessary for more timely, as well as more accurate, updating of the CPI would not be available. In addition, data would not be available to respond to the continuing demand from the public and private sectors for current information on consumer spending.

In the Quarterly Interview Survey, each consumer unit (CU) in the sample is interviewed every three months over four calendar quarters. The sample for each quarter is divided into three panels, with CUs being interviewed every three months in the same panel of every quarter. The Quarterly Interview Survey is designed to collect data on the types of expenditures that respondents can be expected to recall for a period of three months or longer. In general the expenses reported in the Interview Survey are either relatively large, such as property, automobiles, or major appliances, or are expenses which occur on a fairly regular basis, such as rent, utility bills, or insurance premiums.

The Diary (or recordkeeping) Survey is completed at home by the respondent family for two consecutive one-week periods. The primary objective of the Diary Survey is to obtain expenditure data on small, frequently purchased items which normally are difficult to recall over longer periods of time.

II. Current Action

Office of Management and Budget clearance is being sought for the proposed revision of the Consumer Expenditure Surveys: The Quarterly Interview and the Diary.

Additionally, as part of an ongoing effort to improve data quality, maintain or increase response rates, and reduce data collection costs, CE is making the below changes.

Three major changes will be implemented in the Diary Survey (CED). First, in an effort to alleviate burden and slow or reverse the decline in response rates, CE has developed an alternative version of the paper diary form. The new version consolidates the four main diary categories onto two, facing, diary pages so that all expenses for a single day can be entered without flipping pages. An effort was also made to reduce the amount of instructions and examples so that respondents are not confused or intimidated.

Second, the earliest placement date and last placement date restrictions for the Diary will be removed allowing Field Representatives to place the diary on any day within the collection month. Data analysis shows that the monthly expenditures cycles that the earliest and last placement dates were put in place to capture are not statistically significant and were most likely the result of normal random fluctuations in the data that are expected in the survey's data rather than actual expenditure cycles.

Third, in order to simplify procedures and reduce costs, all Diaries will be double placed. With this new procedure, Field Representatives (FRs) will have the entire month to place the diaries instead of 7 days. This should drastically reduce the number of diaries CE loses to the non-interview Type A—Placed Too Late outcome code. As a result, the second Field Representative interview to pick up the Week 1 Diary and place the Week 2 Diary will be eliminated. Data analysis shows that double placements do not appear to have any negative effects on the Diary Survey. Approximately 27% of eligible cases and 33% of completed diaries are currently double placed.

Additionally, CE will delete several tax questions that were deleted from CEQ in 2015 as data received from the IRS have enabled CE to calculate this data rather than collect it.

Several changes will also be implemented in CEQ in order to keep the CEQ questionnaire current. These changes include changes to question wording, deletions, additions, and section restructurings. Questions were added for solar panels, internet away from home charges, and alternative fuels such as electrical vehicle charging; health insurance questions were revamped to make them clearer and to align with the structure of the National Health Interview Survey (NHIS); questions were combined and reworded such as streaming videos to be combined with rental of movies and combining book purchases with book club subscriptions; questions were deleted on purchases occurring in the current month and on purchases of apps, games, and ringtones; questions on refinancing of a property and on construction and repair of property were streamlined.

The Bureau of the Census conducts the CE Surveys for the Bureau of Labor Statistics (BLS) in support of the Consumer Price Index (CPI) program. The continuing CE Surveys provide a constant measurement of changes in consumer expenditure patterns for economic analysis, and obtain data for future CPI revisions. The CPI program anticipates the need for CE surveys to collect outlet information to serve as outlet frames for most commodities and services (C&S) items as issues with TPOPS collection have resulted in prohibitively high costs. To support this objective, CE will test the addition of outlet questions in several sections of the CEQ survey instrument. In all sections except vehicles, CE will add these questions to the fourth interview only; because vehicle purchases are not reported often, questions on the purchase location for vehicles will be asked in all four interviews. Finally, the Incentives/Outlets Test study questions will be deleted.

A full list of the proposed changes to the Quarterly Interview Survey and Diary Survey are available upon request.

In addition to the Incentives/Outlets test, the Consumer Expenditure program is planning several tests over the next several years in an effort to improve the CE surveys in the areas of both data quality and respondent burden.

Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Type of Review: Revision, of a currently approved collection.

Agency: Bureau of Labor Statistics.

Title: The Consumer Expenditure Surveys: The Quarterly Interview and the Diary.

OMB Number: 1220–0050.

Affected Public: Individuals or Households.

TOTAL RESPONSE BURDEN FOR THE QUARTERLY INTERVIEW AND DIARY SURVEYS

	Quarterly	Diary	Total	Incentives/ outlets test in 2017
Number of responses	29,200	27,780	56,980	
Total burden hours	28,974	28,780	57,754	20
Total burden hours including Incentives/Outlets Test	....	....	....	57,774

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 24th day of June 2016.

Kimberley Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2016–15512 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0014]

Proposed Extension of Information Collection; Hazardous Conditions Complaints

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Hazardous Conditions Complaints.

DATES: All comments must be received on or before August 29, 2016.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2016–0019.
- *Regular Mail:* Send comments to USDOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.
- *Hand Delivery:* USDOL—Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 103(g) of the Federal Mine Safety and Health Act of 1977, as amended (Mine Act), a representative of miners, or any individual miner where there is no representative of miners, may submit a written or oral notification of an alleged violation of the Mine Act or a mandatory standard or that an imminent danger exists. The notifier has the right to obtain an immediate inspection by MSHA. A copy of the notice must be provided to the operator, with individual miner names redacted.

MSHA regulations at 30 CFR part 43 implement Section 103(g) of the Mine Act. These regulations provide the procedures for submitting notification of the alleged violation and the actions that MSHA must take after receiving the notice. Although the regulations contain a review procedure (required by section 103(g)(2) of the Mine Act) whereby a miner or a representative of miners may in writing request a review if no citation or order is issued as a result of the original notice, the option is so rarely used that it was not considered in the burden estimates.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Hazardous Conditions Complaints. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The information collection request will be available on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at USDOL—Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Hazardous Conditions Complaints. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0014.

Affected Public: Business or other for-profit.

Number of Respondents: 2,511.

Frequency: On occasion.

Number of Responses: 2,511.

Annual Burden Hours: 502 hours.

Annual Respondent or Recordkeeper Cost: $0.

MSHA Forms: Hazardous Conditions Complaints.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Sheila McConnell,

Certifying Officer.

[FR Doc. 2016–15425 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0041]

Proposed Extension of Information Collection; Program To Prevent Smoking in Hazardous Areas (Pertains to Underground Coal Mines)

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Program to Prevent Smoking in Hazardous Areas (Pertains to Underground Coal Mines).

DATES: All comments must be received on or before August 29, 2016.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2016–0018.
- *Regular Mail:* Send comments to USDOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452
- *Hand Delivery:* USDOL—Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 317(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 877(c), and 30 CFR 75.1702 prohibits persons from smoking or carrying smoking materials underground or in places where there is a fire or explosion hazard. Under the Mine Act, 30 U.S.C. 877(c) and 75.1702, coal mine operators are required to develop programs to prevent persons from carrying smoking materials, matches, or lighters underground and to prevent smoking in hazardous areas, such as in or around oil houses, explosives magazines or other areas where such practice may cause a fire or explosion.

Section 75.1702–1 requires a mine operator to submit a smoking prevention plan to MSHA for approval under § 75.1702 to MSHA for approval. Section 103(h) of the Mine Act, 30 U.S.C. 813, authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners. These information collection requirements help to ensure that a fire or explosion hazard does not occur.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Program to Prevent Smoking in Hazardous Areas (Pertains to Underground Coal Mines). MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

The information collection request will be available on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at USDOL—Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Program to Prevent Smoking in Hazardous Areas (Pertains to Underground Coal Mines). MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0041.

Affected Public: Business or other for-profit.

Number of Respondents: 17.

Frequency: On occasion.

Number of Responses: 17.

Annual Burden Hours: 9 hours.

Annual Respondent or Recordkeeper Cost: $0.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Sheila McConnell,

Certifying Officer.

[FR Doc. 2016–15426 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0138]

Proposed Extension of Information Collection; Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course To Ventilate Working Sections and Areas Where Mechanized Mining Equipment Is Being Installed or Removed

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course to Ventilate Working Sections and Areas Where Mechanized Mining Equipment is Being Installed or Removed.

DATES: All comments must be received on or before August 29, 2016.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number [MSHA–20##–0###]
- *Regular Mail:* Send comments to USDOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.
- *Hand Delivery:* USDOL–Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

MSHA allows operators to use air from a belt air course to ventilate a working section, or an area where mechanized mining equipment is being installed or removed, only under certain conditions. The belt air use must be evaluated and approved by the district manager in the mine ventilation plan and operators must follow a number of other requirements that provide additional protection.

Section 75.350(b) requires that the mine operator must include in a ventilation plan a justification that the use of air from a belt entry would afford at least the same measure of protection as where belt haulage entries are not used. The plan also must include information regarding point feeds and regulators and designated areas for dust and air velocity measurements.

Section 75.351(b)(3) and 75.351(b)(4) require a mine operator to post a map or schematic, at a designated surface location, which shows the locations and type of Atmospheric Monitoring System (AMS) sensors at each location and the intended air flow direction at these locations. This map or schematic must be updated within 24 hours of any change in this information. Contact information for AMS and other appropriate personnel also must be posted at this location.

Section 75.351(j) requires approval of the CO ambient levels, and the means to determine those levels, in the mine ventilation plan.

Section 75.351(m) permits a mine to incorporate time delays into the AMS, or to use other methods for reducing non-fire alerts and alarm levels, provided they are specified and approved in the mine ventilation plan. Permission for such time delays, or other methods of reducing non-fire alerts and alarms, would be granted based on associated documentation that justifies these changes.

Sections 75.351(n)(2) and 75.351(n)(3) require that alarms for AMS be tested every seven days and CO, smoke, or methane sensors be calibrated, every 31 days, respectively.

Section 75.351(o)(1)(i) requires that a record be made if the AMS emits an alert or alarm signal. The record would consist of the date, time, location, and type of sensor, and the reason for its activation.

Section 75.351(o)(1)(ii) requires that, if an AMS malfunctions, a record be made of the date, the extent and cause of the malfunction, and the corrective action taken to return the system to proper operating condition.

Section 75.351(o)(1)(iii) requires that the persons doing the weekly test of alert and alarm signals, the monthly calibration, or maintenance of the system make a record of these tests, calibrations, or maintenance.

Section 75.351(o)(3) requires that all records concerning the AMS be kept in a book or electronically in a computer system that is secure and not susceptible to alteration.

Section 75.351(p) requires the mine operator to keep these records for at least one year at a surface location and to make them available for inspection by authorized representatives of the Secretary and representatives of miners.

Section 75.351(q)(3) requires that a record of annual AMS operator training be kept. The record will include the content of training, the person conducting the training, and the date the training is conducted. The record needs to be maintained at the mine site by the mine operator for at least one year.

Sections 75.352(a), 75.352(b) and 75.352(c) require the designated AMS operator or other appropriate personnel to notify, investigate, or evacuate when malfunction, alert, or alarm signals are received.

Section 75.371(hh) requires reporting within the mine ventilation plan of the "ambient level in parts per million of carbon monoxide, and the method for determining the ambient level, in all areas where carbon monoxide sensors are installed." This provision is impacted by section 75.351(j).

Section 75.371(kk) requires the locations where air quantities are measured as set forth in section 75.350(b)(6) be included in the mine ventilation plan.

Section 75.371(ll) requires the locations and use of point feed regulators, in accordance with Sections 75.350(c) and 75.350(d)(5), to be in the mine ventilation plan.

Section 75.371(mm) requires the location of any diesel-discriminating sensor and additional carbon monoxide or smoke sensors installed in the belt air course to be included in the mine ventilation plan.

Sections 75.371(nn), 75.371(oo), and 75.371(pp) require modification of the mine ventilation plan to show the length of the time delay or any other method used for reducing the number of non-fire related alert and alarm signals from CO sensors, the lower alert and alarm setting for CO sensors, and the alternate instrument and the alert and alarm levels associated with the instrument, respectively.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course to Ventilate Working Sections and Areas Where Mechanized Mining Equipment is Being Installed or Removed. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

The information collection request will be available on *http://www.regulations.gov*. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov*.

The public may also examine publicly available documents at USDOL—Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course to Ventilate Working Sections and Areas Where Mechanized Mining Equipment is Being Installed or Removed. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0138.

Affected Public: Business or other for-profit.

Number of Respondents: 17.

Frequency: On occasion.

Number of Responses: 205.

Annual Burden Hours: 3,442 hours.

Annual Respondent or Recordkeeper Cost: $54,740.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Sheila McConnell,

Certifying Officer.

[FR Doc. 2016–15424 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Affirmative Decisions on Petitions for Modification Granted in Whole or in Part

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and 30 CFR part 44 govern the application, processing, and disposition of petitions for modification. This **Federal Register** Notice notifies the public that MSHA has investigated and issued a final decision on certain mine operator petitions to modify a safety standard.

ADDRESSES: Copies of the final decisions are posted on MSHA's Web site at *http://www.msha.gov/READROOM/PETITION.HTM*. The public may inspect the petitions and final decisions during normal business hours in MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202. All visitors are required to check in at the receptionist's desk in Suite 4E401.

FOR FURTHER INFORMATION CONTACT: Barbara Barron at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Telefax). [These are not toll-free numbers].

SUPPLEMENTARY INFORMATION:

I. Introduction

Under section 101 of the Federal Mine Safety and Health Act of 1977, a mine operator may petition and the Secretary of Labor (Secretary) may modify the application of a mandatory safety standard to that mine if the Secretary determines that: (1) An alternative method exists that will guarantee no less protection for the miners affected than that provided by the standard; or (2) the application of the standard will result in a diminution of safety to the affected miners.

MSHA bases the final decision on the petitioner's statements, any comments and information submitted by interested persons, and a field investigation of the conditions at the mine. In some instances, MSHA may approve a petition for modification on the condition that the mine operator complies with other requirements noted in the decision.

II. Granted Petitions for Modification

On the basis of the findings of MSHA's investigation, and as designee of the Secretary, MSHA has granted or partially granted the following petitions for modification:

- *Docket Number:* M–2013–055–C.

FR Notice: 79 FR 4177 (1/24/2014).

Petitioner: Signal Peak Energy, LLC, 100 Portal Drive, Roundup, Montana 59072.

Mine: Bull Mountains Mine No. 1, MSHA I.D. No. 24–01950, located in Musselshell County, Montana.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

- *Docket Number:* M–2013–060–C.

FR Notice: 79 FR 11141 (2/27/2014).

Petitioner: Kimmel's Mining, Inc., P.O. Box 8, Williamstown, Pennsylvania 17098.

Mine: Williamstown Mine #1, MSHA I.D. No. 36–09435, located in Schuylkill County, Pennsylvania.

Regulation Affected: 30 CFR 75.1400 (Hoisting equipment; general).

- *Docket Number:* M–2014–030–C.

FR Notice: 79 FR 64627 (10/30/2014).

Petitioner: M-Class Mining, LLC, 11351 N. Thompsonville Road, Macedonia, Illinois 62860.

Mine: MC#1 Mine, MSHA I.D. No. 11–03189, located in Franklin County, Illinois.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut return air; permissibility requirements).

- *Docket Number:* M–2015–022–C.

FR Notice: 80 FR 77024 (12/11/2015).

Petitioner: Speed Mining LLC, P.O. Box 99, Dawes, West Virginia 25054.

Mine: Refuse Disposal Facility, MSHA I.D. No. 46–05437, located in Kanawha County, West Virginia.

Regulation Affected: 30 CFR 77.214(a) (Refuse piles; general).

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2016–15435 Filed 6–29–16; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by the MSHA's Office of Standards, Regulations, and Variances on or before August 1, 2016.

ADDRESSES: You may submit your comments, identified by "docket number" on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.
2. *Facsimile:* 202–693–9441.
3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petitions and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or
2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2016–012–C.

Petitioner: ICG Illinois, LLC, 5945 Lester Road, Williamsville, Illinois 62693.

Mine: Viper Mine, MSHA I.D. No. 11–02664, located in Sangamon County, Illinois.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit the use of nonpermissible surveying equipment in or inby the last open crosscut. The petitioner proposes to use theodolites and low-voltage battery operated total stations if they have an IP rating of 66 or higher. The petitioner states that:

(1) Nonpermissible electronic surveying equipment will only be used until equivalent permissible electronic surveying equipment is available or if viable new mechanical surveying equipment is not commercially available.

(2) Viper Mine will maintain a log for electronic surveying equipment. The log will be kept in either a paperbound book or a digital copy. The log will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The log will be made available to MSHA on request.

(3) All nonpermissible electronic surveying equipment to be used in or inby the last open crosscut will be examined by the person that will operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. These checks will include:

(i) Checking the instrument for any physical damage and the integrity of the case.

(ii) Removing the battery and inspecting for corrosion.

(iii) Inspecting the contact points to ensure a secure connection to the battery.

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections.

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(vi) Recording the results of the inspection in the equipment log.

(4) All nonpermissible electronic surveying equipment will be serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment log and will include a description of the work performed.

(5) The non-permissible surveying equipment that will be used in or inby the last open crosscut will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance.

(6) As an additional safety check, prior to setting up and energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the areas appear to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated coal dust is observed, the equipment will not be energized until sufficient rock dust has been applied and/or the accumulations of coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area that is not rocked-dusted within 40 feet of a working face where a continuous miner is used to extract coal, the area will be rock-dusted prior to energizing the electronic surveying equipment.

(7) Prior to energizing any of the nonpermissible surveying equipment in or inby the last open crosscut, methane tests must be made no more than 8 inches from the roof at the location of the equipment. All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors must provide visual and audible warnings when methane is detected at or above 1.0 percent.

(8) All areas to be surveyed will be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 75.361, an additional examination is not required.

(9) A qualified person as defined in 30 CFR 75.151 will continuously monitor for methane immediately before and during the use of nonpermissible surveying equipment in or inby the last open crosscut. If there are two people in the surveying crew, a second person in the crew will also continuously monitor for methane. That second person will either be a qualified person as defined in 30 CFR 75.151 or will be in the process of being trained to be a qualified person but will not make such tests for a period of 6 months, as required by 30 CFR 75.151. On completion of the 6-month training period, the second person on the survey crew must become qualified to continue on the survey crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices. While the equipment is energized in or inby the last open crosscut, one qualified person who is continuously monitoring for methane will remain with the electronic surveying equipment.

(10) Batteries contained in the surveying equipment must be changed out or charged in intake air outby the last open crosscut. Replacement batteries for the electronic surveying equipment will not be brought in or inby the last open crosscut. Upon each entry into the mine, all batteries for the electronic surveying equipment must be fully charged.

(11) When using nonpermissible electronic surveying equipment inby the last open crosscut, the surveyor must confirm by measurement or by the air quantity on the section, on that shift, in the last open crosscut or coming to the face is the quantity that is required by the mine's ventilation plan.

(12) Nonpermissible electronic surveying equipment will not be used when active coal extraction is occurring in the section. All active coal extraction in the section will cease prior to use of the equipment in or inby the last open crosscut.

(13) Personnel using the surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.

(14) All members of the surveying crew will receive specific training on the terms and conditions of this petition before using nonpermissible electronic surveying equipment in or inby the last open crosscut. A record of the training will be kept with the other training records.

(15) Within 60 days after the Proposed Decision and Order (PDO) becomes final, the petitioner will submit proposed revisions for their approved part 48 training plan to the District Manager. The revisions will specify initial and refresher training regarding the terms and conditions in the PDO. When training is conducted on the terms and conditions stated in the PDO, an MSHA Certificate of Training (Form 5000–23) will be completed. Comments on the certificate of training will indicate surveyor training.

(16) Viper mine will replace or exclude from service any theodolite that was acquired more than 5 years prior to the date that this petition becomes final or any total station acquired more than 10 years prior to the day that the PDO becomes final for use in or inby the last open crosscut. After 5 years, Viper Mine will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from date of manufacture and total stations will be no more than 10 years from date of manufacture of use in or inby the last open crosscut.

(17) Viper Mine is responsible for seeing that all surveying contractors hired by Viper Mine are using relatively new electronic equipment, *i.e.,* theodolites no older than 5 years from date of manufacture and total stations no older than 10 years from date of manufacture. These rules and regulations will apply to all nonpermissible electronic surveying equipment used in or inby the last open crosscut regardless of whether the equipment is used by Viper Mine or by an independent contractor.

(18) Nonpermissible equipment will not be used where float coal dust is in suspension.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2016–013–C.

Petitioner: ICG Illinois, LLC, 5945 Lester Road, Williamsville, Illinois 62693.

Mine: Viper Mine, MSHA I.D. No. 11–02664, located in Sangamon County, Illinois.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard to permit the use of nonpermissible surveying equipment in the return airway. The petitioner proposes to use theodolites and low-voltage battery-operated total stations if they have an IP rating of 66 or higher. The petitioner states that:

(1) Nonpermissible electronic surveying equipment will only be used until equivalent permissible electronic surveying equipment is available or if viable new mechanical surveying equipment is not commercially available.

(2) Viper Mine will maintain a log for electronic surveying equipment. The log will be kept in either a paperbound book or a digital copy. The log will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The log will be made available to MSHA on request.

(3) All nonpermissible electronic surveying equipment to be used in the return airway will be examined by the person that will operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. These checks will include:

(i) Checking the instrument for any physical damage and the integrity of the case.

(ii) Removing the battery and inspecting for corrosion.

(iii) Inspecting the contact points to ensure a secure connection to the battery.

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections.

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(vi) Recording the results of the inspection in the equipment log.

(4) All nonpermissible electronic surveying equipment will be serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment log and

will include a description of the work performed.

(5) The nonpermissible surveying equipment used in the return airway will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance.

(6) As an additional safety check, prior to setting up and energizing nonpermissible electronic surveying equipment in the return airway, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the areas appear to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated coal dust is observed, the equipment will not be energized until sufficient rock dust has been applied and/or the accumulations of coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area that is not rocked-dusted within 40 feet of a working face where a continuous miner is used to extract coal, the area will be rock-dusted prior to energizing the electronic surveying equipment.

(7) Prior to energizing any of the nonpermissible surveying equipment in the return airway, methane tests must be made no more than 8 inches from the roof at the location of the equipment. All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors must provide visual and audible warnings when methane is detected at or above 1.0 percent.

(8) All areas to be surveyed will be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 75.361, an additional examination is not required.

(9) A qualified person as defined in 30 CFR 75.151 will continuously monitor for methane immediately before and during the use of nonpermissible surveying equipment in the return airway. If there are two people in the surveying crew, a second person in the crew will also continuously monitor for methane. That second person will either be a qualified person as defined in 30 CFR 75.151 or will be in the process of being trained to be a qualified person but will not make such tests for a period of 6 months, as required by 30 CFR 75.151. On completion of the 6-month training period, the second person on the survey crew must become qualified to continue on the survey crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices. While the equipment is energized in the return airway, one qualified person who is continuously monitoring for methane will remain with the electronic surveying equipment.

(10) Batteries contained in the surveying equipment must be changed out or charged in intake air out of a return airway. Replacement batteries for the electronic surveying equipment will not be brought into the return airway. Upon each entry into the mine, all batteries for the electronic surveying equipment must be fully charged.

(11) When using nonpermissible electronic surveying equipment in the return airway, the surveyor must confirm by measurement or by the air quantity on the section, on that shift, in the return airway is the quantity that is required by the mine's ventilation plan.

(12) Nonpermissible electronic surveying equipment will not be used when active coal extraction is occurring in the section. All active coal extraction in the section will cease prior to use of the equipment in the return airway.

(13) Personnel using the surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.

(14) All members of the surveying crew will receive specific training on the terms and conditions of this petition before using nonpermissible electronic surveying equipment in the return airway. A record of the training will be kept with the other training records.

(15) Within 60 days after the Proposed Decision and Order (PDO) becomes final, the petitioner will submit proposed revisions for their approved part 48 training plan to the District Manager. The revisions will specify initial and refresher training regarding the terms and conditions in the PDO. When training is conducted on the terms and conditions stated in the PDO, an MSHA Certificate of Training (Form 5000–23) will be completed. Comments on the certificate of training will indicate surveyor training.

(16) Viper mine will replace or exclude from service any theodolite that was acquired more than 5 years prior to the date that this petition becomes final or any total station acquired more than 10 years prior to the day that the PDO becomes final for use in the return airway. After 5 years, Viper Mine will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from date of manufacture and total stations will be no more than 10 years from date of manufacture for use in the return airway.

(17) Viper Mine is responsible for seeing that all surveying contractors hired by Viper Mine are using relatively new electronic equipment, *i.e.,* theodolites no older than 5 five years from date of manufacture and total stations no older than 10 years from date of manufacture. These rules and regulations will apply to all nonpermissible electronic surveying equipment used in the return airway regardless of whether the equipment is used by Viper Mine or by an independent contractor.

(18) Nonpermissible equipment will not be used where float coal dust is in suspension.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2016–014–C.

Petitioner: ICG Illinois, LLC, 5945 Lester Road, Williamsville, Illinois 62693.

Mine: Viper Mine, MSHA I.D. No. 11–02664, located in Sangamon County, Illinois.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard to permit the use of nonpermissible surveying equipment within 150 feet of pillar workings. The petitioner proposes to use theodolites and low-voltage battery-operated total stations if they have an IP rating of 66 or higher. The petitioner states that:

(1) Nonpermissible electronic surveying equipment will only be used until equivalent permissible electronic surveying equipment is available or if viable new mechanical surveying equipment is not commercially available.

(2) Viper Mine will maintain a log for electronic surveying equipment. The log will be kept in either a paperbound book or a digital copy. The log will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The log will be made available to MSHA on request.

(3) All nonpermissible electronic surveying equipment to be used within 150 feet of pillar workings be examined by the person that will operate the equipment prior to taking the equipment underground to ensure the

equipment is being maintained in a safe operating condition. These checks will include:

(i) Checking the instrument for any physical damage and the integrity of the case.

(ii) Removing the battery and inspecting for corrosion.

(iii) Inspecting the contact points to ensure a secure connection to the battery.

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections.

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(vi) Recording the results of the inspection in the equipment log.

(4) All nonpermissible electronic surveying equipment will be serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment log and will include a description of the work performed.

(5) The nonpermissible surveying equipment that will be used within 150 feet of pillar workings will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance.

(6) As an additional safety check, prior to setting up and energizing nonpermissible electronic surveying equipment within 150 feet of pillar workings, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the areas appear to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated coal dust is observed, the equipment will not be energized until sufficient rock dust has been applied and/or the accumulations of coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area that is not rocked-dusted within 40 feet of a working face where a continuous miner is used to extract coal, the area will be rock- dusted prior to energizing the electronic surveying equipment.

(7) Prior to energizing any of the nonpermissible surveying equipment within 150 feet of pillar workings, methane tests must be made no more than 8 inches from the roof at the location of the equipment. All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors must provide visual and audible warnings when methane is detected at or above 1.0 percent.

(8) All areas to be surveyed will be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 75.361, an additional examination is not required.

(9) A qualified person as defined in 30 CFR 75.151 will continuously monitor for methane immediately before and during the use of nonpermissible surveying equipment within 150 feet of pillar workings. If there are two people in the crew, a second person in the surveying crew will also continuously monitor for methane. That second person will either be a qualified person as defined in 30 CFR 75.151 or will be in the process of being trained to be a qualified person but will not make such tests for a period of 6 months, as required by 30 CFR 75.151. On completion of the 6-month training period, the second person on the survey crew must become qualified to continue on the survey crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices. While the equipment is energized within 150 feet of pillar workings, one qualified person who is continuously monitoring for methane will remain with the electronic surveying equipment.

(10) Batteries contained in the surveying equipment must be changed out or charged in intake air outside of 150 feet of pillar workings. Replacement batteries for the electronic surveying equipment will not be brought within 150 feet of pillar workings. Upon each entry into the mine, all batteries for the electronic surveying equipment must be fully charged.

(11) When using nonpermissible electronic surveying equipment within 150 feet of pillar workings, the surveyor must confirm by measurement or by the air quantity on the section, on that shift, within 150 feet of pillar workings is the quantity that is required by the mine's ventilation plan.

(12) Nonpermissible electronic surveying equipment will not be used when active coal extraction is occurring in the section. All active coal extraction in the section will cease prior to use of the equipment within 150 feet of pillar workings.

(13) Personnel using the surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of surveying equipment in areas where methane could be present.

(14) All members of the surveying crew will receive specific training on the terms and conditions of this petition before using nonpermissible electronic surveying equipment within 150 feet of pillar workings. A record of the training will be kept with the other training records.

(15) Within 60 days after the Proposed Decision and Order (PDO) becomes final, the petitioner will submit proposed revisions for their approved part 48 training plan to the District Manager. The revisions will specify initial and refresher training regarding the terms and conditions in the PDO. When training is conducted on the terms and conditions stated in the PDO, an MSHA Certificate of Training (Form 5000–23) will be completed. Comments on the certificate of training will indicate surveyor training.

(16) Viper mine will replace or exclude from service any theodolite that was acquired more than 5 years prior to the date that this petition becomes final or any total station acquired more than 10 years prior to the day that the PDO becomes final for use within 150 feet of pillar workings. After 5 years, Viper Mine will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from date of manufacture and total stations will be no more than 10 years from date of manufacture for use within 150 feet of pillar workings.

(17) Viper Mine is responsible for seeing that all surveying contractors hired by Viper Mine are using relatively new electronic equipment, *i.e.*, theodolites no older than 5 years from date of manufacture and total stations no older than 10 years from date of manufacture. These rules and regulations will apply to all nonpermissible electronic surveying equipment used within 150 feet of pillar workings regardless of whether the equipment is used by Viper Mine or by an independent contractor.

(18) Nonpermissible equipment will not be used where float coal dust is in suspension.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2016–15436 Filed 6–29–16; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2015–0014]

Maritime Advisory Committee for Occupational Safety and Health

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of Maritime Advisory Committee for Occupational Safety and Health (MACOSH) meeting.

SUMMARY: This **Federal Register** notice announces meetings of the full Committee and the workgroups on August 9 and 10, 2016 in Washington, DC.

DATES: *MACOSH meeting:* MACOSH will meet from 9 a.m. until approximately 5 p.m. on August 9 and 10, 2016.

Submission of comments, requests to speak, and requests for special accommodation: Submit comments, requests to speak at the full Committee meeting, and requests for special accommodations for these meetings (postmarked, sent, or transmitted) by July 25, 2016.

ADDRESSES: The Committee and workgroups will meet at the U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW., Washington, DC 20210, in Conference Room S–4215. Meeting attendees must use the visitor's entrance located at 3rd & C Streets NW.

Submission of comments and requests to speak: Submit comments and requests to speak at the MACOSH meetings, identified by the docket number for this **Federal Register** notice (Docket No. OSHA 2015–0014), by one of the following methods:

Electronically: Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If comments, including attachments, are not longer than 10 pages, commenters may fax them to the OSHA Docket Office at (202) 693–1648.

Regular mail, express mail, hand (courier) delivery, and messenger service: When using this method, submit a copy of comments and attachments to the OSHA Docket Office, Docket No. OSHA–2015–0014, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. The Docket Office accepts deliveries (express mail, hand (courier) delivery, and messenger service) during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Requests for special accommodations: Submit requests for special accommodations for MACOSH and its workgroup meetings by hard copy, telephone, or email to: Gretta Jameson, OSHA, Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *jameson.grettah@dol.gov.*

Instructions: All submissions must include the Agency name and docket number for this **Federal Register** notice (Docket No. OSHA–2015–0014). Because of security-related procedures, submissions by regular mail may result in a significant delay in receipt. Please contact the OSHA Docket Office for information about security procedures for making submissions by express mail, hand (courier) delivery, and messenger service.

OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

Docket: To read or download documents in the public docket for this MACOSH meeting, go to *http://www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *http://www.regulations.gov.* All submissions are available for inspection and, when permitted, copying at the OSHA Docket Office at the above address. For information on using *http://www.regulations.gov* to make submissions or to access the docket, click on the "Help" tab at the top of the Home page. Contact the OSHA Docket Office for information about materials not available through that Web site and for assistance in using the Internet to locate submissions and other documents in the docket.

FOR FURTHER INFORMATION CONTACT: *For press inquiries:* Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, Room N–3647, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.frank2@dol.gov.*

For general information about MACOSH and this meeting: Amy Wangdahl, Director, Office of Maritime and Agriculture, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2066; email: *wangdahl.amy@dol.gov.*

Copies of this **Federal Register** notice: Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available at OSHA's Web page at: *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION: All MACOSH committee and workgroup meetings are open to the public. Interested persons may attend the full Committee and its workgroup meetings at the time and place listed above. The Longshoring and Shipyard workgroups will meet from 9 a.m. until approximately 5 p.m. on August 9, 2016, in Conference Rooms S–4215A and S–4215C. The workgroups will discuss protecting workers from toxic preservative coatings, personal protective equipment in shipyards, assessing current provisions of 29 CFR part 1915 subpart E, lashing safety, and mechanic safety.

The full Committee will meet from 9 a.m. until approximately 5 p.m. on August 10, 2016, in Conference Room S–4215. The tentative agenda will include: Updates from OSHA National Office Directorates; updates on maritime enforcement activities from OSHA Regions; and reports from the Longshoring and Shipyard workgroups.

Public Participation: Any individual attending the MACOSH meeting, including the workgroup meetings, at the U.S. Department of Labor, Frances Perkins Building, must use the entrance located at 3rd & C Streets NW and pass through Building Security. Attendees must have valid government-issued photo identification to enter the building. Please contact Gretta Jameson at (202) 693–2176 (email: *jameson.grettah@dol.gov*) for additional information about building security measures for attending the MACOSH Committee and workgroup meetings. Interested parties may submit a request to make an oral presentation to MACOSH by any one of the methods listed in the **ADDRESSES** section above. The request must state the amount of time requested to speak, the interest represented (*e.g.,* organization name), if any, and a brief outline of the presentation. The MACOSH Chair has discretion to grant requests to address the full Committee as time permits.

Interested parties also may submit written comments, including data and other information, using any one of the methods listed in the **ADDRESSES** section above. OSHA will provide all submissions to MACOSH members prior to the meeting. Individuals who need special accommodations to attend the MACOSH meeting should contact Gretta Jameson as specified above under the heading "Requests for special accommodations" in the **ADDRESSES** section.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 29 U.S.C. 655, 656, 5 U.S.C. App. 2, Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR part 1912.

Signed at Washington, DC, on June 27, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–15513 Filed 6–29–16; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 1 meeting of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: All meetings are Eastern time and ending times are approximate:

Design (review of applications): This meeting will be closed.

Date and time: July 18, 2016; 12:00 p.m. to 12:30 p.m.

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *plowitzk@arts.gov,* or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

Dated: June 27, 2016.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2016–15538 Filed 6–29–16; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data is provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents is properly assessed. Currently, the National Endowment for the Arts is soliciting comments concerning the proposed information collection of: Blanket Justification for NEA Funding Application Guidelines and Reporting Requirements. A copy of the current information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within 60 days from the date of this publication in the **Federal Register**. We are particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Can help the agency minimize the burden of the collection of information on those who are to respond, including through the electronic submission of responses.

ADDRESSES: Send comments to Jillian Miller, Director, Office of Guidelines and Panel Operations, National Endowment for the Arts, at *guidelines@arts.gov.*

Kathy Daum,

Director, Administrative Services, National Endowment for the Arts.

[FR Doc. 2016–15521 Filed 6–29–16; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

NAME: Advisory Committee for Mathematical and Physical Sciences (#66) (Virtual).

DATE/TIME: July 21, 2016; 1:30 p.m. to 3:30 p.m.

PLACE: National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Virtual Meeting.

JOIN THROUGH: *https://nsf.webex.com/mw3100/mywebex/default.do?service=1&siteurl=nsf&nomenu=true&main_url=%2Fmc3100%2Fe.do%3Fsiteurl%3Dnsf%26AT%3DMI%26EventID%3D446052942%26UID%3D0%26Host%3DQUhTSwAAAAIa7Z3IWDC3PczHy6EYVXAoaGxla959d8CrKHj81feoXVtIhaskft_PE-740G6YRrSx5X9K35L2m7JlzX_hmGwI0%26FrameSet%3D2%26MTID%3Dmae8a8a97ec989c2dc13ec21465039142.*

TYPE OF MEETING: Open.

CONTACT PERSON: Eduardo Misawa, National Science Foundation, 4201 Wilson Boulevard, Suite 505, Arlington, Virginia 22230; Telephone 703–292–8300.

PURPOSE OF MEETING: To provide advice, recommendations and counsel on major goals and policies pertaining to mathematical and physical sciences programs and activities.

Agenda

Thursday, July 21, 2016

1:30–1:45 p.m.: Meeting opening, FACA briefing and approval of April meeting minutes
Juan de Pablo, MPS Advisory Committee Chair
Fleming Crim, Assistant Director, Directorate for Mathematical and Physical Sciences
Eduardo Misawa, Staff Associate, MPS Office of the Assistant Director
1:45–2:45 p.m.: Division of Chemistry Committee of Visitor (COV)'s report
Sharon Hammes-Schiffer, COV Chair
Juan de Pablo, MPS Advisory Committee Chair
2:45–3:30 p.m.: New Business and Discussions
3:30 p.m.: Adjourn

Dated: June 27, 2016.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2016–15489 Filed 6–29–16; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board's Executive Committee, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

DATE & TIME: Tuesday, July 5, 2016 from 4:00–5:00 p.m. EDT.

SUBJECT MATTER: (1) Committee Chair's opening remarks; (2) Approval of Executive Committee minutes of April 2016; (3) Discuss issues and topics for an agenda of the NSB meeting scheduled for August 9–10, 2016; and (4) Committee Chair's closing remarks.

STATUS: Open.

LOCATION: This meeting will be held by teleconference at the National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. A public listening line will be available. Members of the public must contact the Board Office (call 703–292–7000 or send an email message to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the teleconference for the public listening number.

UPDATES & POINT OF CONTACT: Please refer to the National Science Board Web site *www.nsf.gov/nsb* for additional information. Meeting information and updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/notices/.* Point of contact for this meeting is: James Hamos, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292–8000.

Chris Blair,

Executive Assistant to the NSB Office.

[FR Doc. 2016–15720 Filed 6–28–16; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–285; NRC–2015–0261]

Omaha Public Power District; Fort Calhoun Station, Unit No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Omaha Public Power District to withdraw its application dated September 10, 2015, for a proposed amendment to Facility Operating License No. DPR–40. The proposed amendment would have revised the Updated Safety Analysis Report (USAR) to allow the use of the equipment classification methodology in industry standard American National Standards Institute/American Nuclear Society (ANSI/ANS)–58.14–2011, "Safety and Pressure Integrity Classification Criteria for Light Water Reactors."

DATES: June 30, 2016.

ADDRESSES: Please refer to Docket ID NRC–2015–0261 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0261. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Carl F. Lyon, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–2296, email: *Fred.Lyon@nrc.gov.*

SUPPLEMENTARY INFORMATION:

The NRC has granted the request of Omaha Public Power District (the licensee) to withdraw its September 10, 2015, application (ADAMS Accession No. ML15258A680), for proposed amendment to Facility Operating License No. DPR–40 for the Fort Calhoun Station, Unit No. 1, located in Washington County, Nebraska.

The proposed amendment would have revised the USAR to allow the use of the equipment classification methodology in industry standard ANSI/ANS–58.14–2011, "Safety and Pressure Integrity Classification Criteria for Light Water Reactors."

The licensee's application was previously noticed in the **Federal Register** on November 24, 2015 (80 FR 73238). The licensee provided a response to an NRC staff request for additional information related to this action on April 8, 2016, and a request to withdraw the application on June 20, 2016 (ADAMS Accession Nos. ML16099A173 and ML16172A279, respectively).

Dated at Rockville, Maryland, this 24th day of June 2016.

For the Nuclear Regulatory Commission.

Carl F. Lyon,

Project Manager, Plant Licensing Branch IV–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–15544 Filed 6–29–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–16; NRC–2014–0154]

North Anna Power Station Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering a license amendment request for the Virginia Electric and Power Company's (Dominion) Special Nuclear Materials (SNM) License SNM–2507 for the operation of North Anna Power Station's (NAPS) independent spent fuel storage installation (ISFSI). The proposed amendment would revise the technical specifications (TSs) to allow the loading and storing of high burnup spent nuclear fuel from NAPS, Units 1 and 2, in a single, modified (and instrumented) TN–32B HBU cask.

DATES: The environmental assessment and finding of no significant impact referenced in this document are available on June 30, 2016.

ADDRESSES: Please refer to Docket ID NRC–2014–0154 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0154. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jean Trefethen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0867, email: *Jean.Trefethen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of a license amendment for Dominion's SNM License SNM–2507 for the NAPS ISFSI located in Louisa County, Virginia (ADAMS Accession No. ML15239B251 and ML15289A189). Dominion is proposing to revise the TSs to allow the loading and storing of high burnup spent nuclear fuel (*i.e.,* spent fuel with burnup greater than 45,000 megawatt days per metric ton of uranium (MWD/MTU)) from NAPS, Units 1 and 2, in a single, modified (and instrumented) TN–32B HBU cask.

The NRC staff has prepared a final environmental assessment (EA) as part of its review of this proposed license amendment in accordance with the requirements in part 51 of title 10 of the *Code of Federal Regulations* (10 CFR) "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Based on the final EA, the NRC has determined that an environmental impact statement is not required for this proposed action and a finding of no significant impact (FONSI) is appropriate. The NRC is also conducting a safety evaluation of the proposed license amendment pursuant to 10 CFR part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor-Related Greater than Class C Waste," and the results will be documented in a separate Safety Evaluation Report (SER). If Dominion's request is approved, the NRC will issue the license amendment following publication of this final EA and FONSI and the SER.

II. Final Environmental Assessment Summary

Dominion is requesting to amend its specifically-licensed ISFSI to load and store high burnup spent nuclear fuel from NAPS, Units 1 and 2, in a single, modified (and instrumented) TN–32B HBU cask. Specifically, the TN–32B HBU cask will be modified to insert thermocouples through the cask lid and into the fuel assemblies to monitor fuel temperatures in the cask. The data gathered will support the U.S. Department of Energy and Electric Power Research Institute High Burnup Dry Storage Research Project. Dominion is proposing to revise the TSs that address the functional and operating limits, the limiting condition for operation, and the design features to reflect the use of the TN–32B HBU cask. As part of the High Burnup Dry Storage Research Project, Dominion will monitor the fuel temperature in this cask and collect data to support research on the long-term behavior of high burnup spent nuclear fuel. The information will be used to inform dry cask designs and future ISFSI licensing actions. If the proposed license amendment is approved, Dominion will load the TN–32B HBU cask with high burnup spent nuclear fuel and place it on the single vacant spot in the specifically-licensed ISFSI Pad 1.

The NRC has assessed the potential environmental impacts of the proposed action, and alternatives to the proposed action including the use of the Transnuclear, Inc., Standardized NUHOMS® Cask System under the generally-licensed ISFSI and the no-action alternative. The results of the NRC's environmental review can be found in the final EA (ADAMS Accession No. ML16168A104). The NRC staff performed its environmental review in accordance with the requirements in 10 CFR part 51. In conducting the environmental review, the NRC considered information in the license amendment application (ADAMS Accession No. ML15239B251); information in the responses to the NRC's requests for additional information (ADAMS Accession No. ML16097A213 and ML16097A219); communications and consultation with the Virginia State Historic Preservation Office, the U.S Fish and Wildlife Service (FWS), and the Virginia Department of Health.

Approval of Dominion's proposed license amendment would allow the TN–32B HBU cask to be placed on the specifically-licensed ISFSI Pad 1. Changes to routine operations or maintenance of the NAPS specifically-licensed ISFSI would consist of downloading the data from the data logger on a quarterly basis. Dominion calculated the total dose rate at the site boundary from the placement of this one TN–32B HBU cask and determined that the dose would be 0.937 mrem/year. Adding the total dose rate from the placement of the TN–32B HBU cask to the maximum combined radiation contribution to the nearest permanent resident from the operation of the ISFSI and the NAPS, Units 1 and 2 (5.10 mrem/year), would result in a total combined dose rate of 6.037 mrem/year, which is below the 25 mrem/year regulatory limit in 10 CFR 72.104. In addition, the NRC reviews and oversees casks to ensure these are designed and maintained in accordance with the regulatory limits in 10 CFR parts 20 and 72. Furthermore, Dominion maintains a radiation protection program for NAPS, Units 1 and 2, and the specifically-licensed and generally-licensed ISFSIs in accordance with 10 CFR part 20 to ensure that radiation doses are as low as is reasonably achievable. Accordingly, no significant radiological or non-radiological impacts are expected to result from approval of the license amendment request, and the proposed action would not significantly contribute to cumulative impacts at the NAPS site. Additionally, there would be no disproportionately high and adverse impacts on minority and low-income populations. Furthermore, the NRC staff determined that this license amendment request does not have the potential to cause effects on historic properties, assuming those were present; therefore, in accordance with 36 CFR 800.3(a)(1), no consultation is required under Section 106 of the National Historic Preservation Act. The NRC staff, however, reached out to and informed the Virginia State Historic Preservation Officer and the Pamunkey Tribe of Virginia of its determination via letters dated April 12, 2016, and January 21, 2016, respectively (ADAMS Accession No. ML16098A212 and ML16020A342, respectively). The NRC staff also consulted with the FWS in accordance with Section 7 of the Endangered Species Act. The NRC staff used FWS Virginia Field Office's Ecological Services online project review process. The self-certification letter dated April 8, 2016 (ADAMS Accession No. ML16118A168), stated that "additional coordination with this office is not needed." The NRC completed the certification process by submitting the online review package to the FWS Virginia Field Office via letter dated May 2, 2016 (ADAMS Accession No. ML16120A189). In conclusion, the NRC staff finds that the proposed action will not result in a significant effect on the quality of the human environment.

III. Finding of No Significant Impact

Based on its review of the proposed action, in accordance with the requirements in 10 CFR part 51, the NRC has concluded that the license amendment request for the Dominion's SNM License Number SNM–2507 for the operation of NAPS' ISFSI located in Louisa County, Virginia, will not significantly affect the quality of the human environment. Therefore, the NRC has determined, pursuant to 10 CFR 51.31, that preparation of an environmental impact statement is not required for the proposed action and a finding of no significant impacts is appropriate.

Dated at Rockville, Maryland, this 24th day of June, 2016.

For the Nuclear Regulatory Commission.

Craig E. Erlanger,

Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2016–15573 Filed 6–29–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Vogtle Electric Generating Plant Unit 3; Southern Nuclear Operating Company, Inc.; Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia

AGENCY: Nuclear Regulatory Commission.

ACTION: Grant of exemption; approval of alternative.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption from the requirements of the Commission's regulations that require a portion of the operating test, which is part of the operator licensing examination, to be administered in a plant walk-through and approving alternative examination criteria in response to a May 27, 2016, request from Southern Nuclear Operating Company (SNC or facility licensee).

DATES: This exemption is effective as of June 24, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that a document is referenced. The facility licensee's exemption request was submitted to the NRC by letter dated May 27, 2016 (ADAMS Accession No. ML16148A484).
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Paul Kallan, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2809; email: *Paul.Kallan@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Southern Nuclear Operating Company, Inc. (SNC or facility licensee); Georgia Power Company; Oglethorpe Power Corporation; MEAG Power SPVM, LLC.; MEAG Power SPVJ, LLC.; MEAG Power SPVP, LLC.; and the City of Dalton, Georgia (together, the "VEGP Owners"); are the holders of Combined License (COL) Nos. NPF–91 and NPF–92, which authorize the construction and operation of VEGP Units 3 and 4, respectively.[1] VEGP Units 3 and 4 are Westinghouse AP1000 pressurized-water reactors under construction in Burke County, Georgia. They are co-located with VEGP Units 1 and 2, which are two operating Westinghouse four-loop pressurized-water reactors.

VEGP Unit 3 is under construction and most of the plant systems have not been built. The facility licensee requests an exemption from the portion of section 55.45(b) of title 10 of the *Code of Federal Regulations* (10 CFR), requiring that the "the [operator and senior operator] operating test will be administered in a plant walkthrough." Pursuant to 10 CFR 55.11, the "Commission may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest."

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[1] SNC is authorized by the VEGP Owners to exercise responsibility and control over the physical construction, operation, and maintenance of the facility, and is the "facility licensee" as defined in 10 CFR 55.4 for purposes of this evaluation.

As an alternative to the in-plant methods of testing described in NUREG–1021, "Operator Licensing Examination Standards for Power Reactors," the facility licensee proposed that applicants for operator and senior operator licenses at VEGP Unit 3 be tested using discussion and performance methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups. Approval of proposed alternatives is addressed in NUREG–1021, ES–201, "Initial Operator Licensing Examination Process," Section B, "Background." As stated therein,

> Facility licensees may propose alternatives to the examination criteria contained here and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The NRC staff will review any proposed alternatives and make a decision regarding their acceptability. The NRC will not approve any alternative that would compromise the agency's statutory responsibility to prescribe uniform conditions for the operator licensing examinations.

The facility licensee also requested an exemption from 10 CFR 55.40(a) and (b), which require, in part, the Commission and facility licensees to prepare the operating tests required by 10 CFR 55.45 in accordance with the criteria in NUREG–1021, because ES–301, Section D.4.a requires in-plant system job performance measures (JPMs) be performed in the plant and Section D.4.b requires that one JPM be performed in the radiologically controlled area (RCA) as part of the walk-through administered to applicants during the operating test. However, the NRC staff determined that no exemption to the requirement to use the examination criteria in NUREG–1021, as stated in 10 CFR 55.40(a) and (b), is necessary because ES–201 allows for the consideration of alternatives. In other words, NUREG–1021 allows alternative testing methods to be used as long as an alternative does not compromise the agency's statutory responsibility to prescribe uniform conditions.

Requirements for Operator Licensing Examinations

The Commission's regulations in 10 CFR part 55, "Operators' Licenses," in part establish procedures and criteria for the issuance of licenses to operators and senior operators of utilization facilities licensed under the Atomic Energy Act of 1954, as amended, and 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Per 10 CFR 55.51, "Issuance of Licenses," "If the Commission determines that an applicant for an operator license or a senior operator license meets the requirements of the Act and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary." Section 55.33(a) states in part that the Commission will approve an initial application for a license if it finds that (1) the applicant's health is sufficient and (2) the applicant has passed the requisite written examination and operating test in accordance with 10 CFR 55.41, "Written Examination: Operators," or 10 CFR 55.43, "Written Examination: Senior Operators," and 10 CFR 55.45, "Operating Tests." These examinations and tests determine whether the applicant for an operator license has learned to operate a facility competently and safely, and additionally, in the case of a senior operator, whether the applicant has learned to direct the licensed activities of licensed operators competently and safely.

The regulations in 10 CFR 55.40(a) require the Commission to use the criteria in NUREG–1021, "Operator Licensing Examination Standards for Power Reactors," in effect 6 months before the examination date to prepare the written examinations required by 10 CFR 55.41 and 55.43 and the operating tests required by 10 CFR 55.45; 10 CFR 55.40(a) also requires the Commission to use the criteria in NUREG–1021 to evaluate the written examinations and operating tests prepared by power reactor facility licensees pursuant to 10 CFR 55.40(b).

As stated in 10 CFR 55.40(b), power reactor facility licensees may prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and may prepare the operating tests required by 10 CFR 55.45, subject to the following conditions: (1) They shall prepare the required examinations and tests in accordance with the criteria in NUREG–1021 as described in 10 CFR 55.40(a); (2) pursuant to 10 CFR 55.49, they shall establish, implement, and maintain procedures to control examination security and integrity; (3) an authorized representative of the facility licensee shall approve the required examinations and tests before they are submitted to the Commission for review and approval; and (4) they must receive Commission approval of their proposed written examinations and operating tests.

In accordance with 10 CFR 55.45(a), "[t]he operating test, to the extent applicable, requires the applicant to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a representative sample from among . . . 13 [listed] items." In accordance with 10 CFR 55.45(b):

> *Implementation—Administration.* The operating test will be administered in a plant walkthrough and in either—
>
> (1) A simulation facility that the Commission has approved for use after application has been made by the facility licensee under § 55.46(b);
>
> (2) A plant-referenced simulator (§ 55.46(c)); or
>
> (3) The plant, if approved for use in the administration of the operating test by the Commission under § 55.46(b).

The "in a plant walkthrough" portion of 10 CFR 55.45(b) is the subject of the exemption request.

NUREG–1021, Revision 10 (December 2014) (ADAMS Accession No. ML14352A297) establishes the policies, procedures, and practices for examining applicants for operator and senior operator licenses and licensees pursuant to 10 CFR part 55; it contains the examination standards that ensure the equitable and consistent administration of operator licensing examinations. NUREG–1021 is organized by topic into chapters designated with "ES," which stands for "examination standard." As relevant here, Chapter 2 (ES–2xx) addresses initial pre-examination activities and Chapter 3 (ES–3xx) addresses initial operating tests. Chapter 3 includes ES–301, "Preparing Initial Operating Tests," and ES–302, "Administering Operating Tests to Initial License Applicants."

NRC examiners and facility licensees use NUREG–1021 together with the applicable NRC knowledge and abilities (K/A) catalog. NUREG–2103, "Knowledge and Abilities Catalog for Nuclear Power Plant Operators: Westinghouse AP1000 Pressurized-Water Reactors," was developed specifically to address the passive nature of the Westinghouse AP1000 design. The NRC K/A catalogs provide the basis for the development of content-valid operator licensing examinations. NUREG–1021, Appendix A, "Overview of Generic Examination Concepts," Section C.1, "Content Validity," describes that a content-valid examination establishes a link between the examination and the duties that the applicants will perform on the job. Also, this section states,

> Test items selected for inclusion in an NRC examination should be based on K/As contained in the appropriate K/A catalog. Testing outside the documented K/As can jeopardize the content validity of the examination. Content validity can also be

reduced if important K/As are omitted from the examination.

The NRC K/A catalogs contain K/A statements that have been rated for their importance with respect to the safe operation of the plant. An importance rating less than 2.5 represents a K/A statement of limited importance for the safe operation of a plant. Such statements are generally considered as inappropriate content for NRC licensing examinations.

Operator licensing examinations developed using the applicable NRC K/A catalog along with the guidance in NUREG–1021 will sample the 13 items listed in 10 CFR 55.45(a) and also ensure that exam topics are associated with K/A statements of significant importance for the safe operation of the plant. Thus, the examinations will be content-valid.

The Operating Test

NUREG–1021, Revision 10, ES–301, "Preparing Initial Operating Tests," Section B, "Background," describes that the requirements in 10 CFR 55.45 for the operating test are met by administering a simulator test and a walk-through.

The simulator test is typically administered in a team format with up to three applicants in the main control room simulator. It implements Items 1–8 and 11–13 of 10 CFR 55.45(a) and is the most performance-based aspect of the operating test. NRC examiners use the simulator test to evaluate each applicant's ability to safely operate the plant systems under dynamic, integrated conditions.

In contrast, the NRC examiners administer the walk-through to applicants one-on-one. The walk-through consists of two parts: Administrative topics and control room/in-plant systems. The administrative topics part of the walk-through implements Items 9–12 of 10 CFR 55.45(a) and covers K/As associated with administrative control of the plant. The control room/in-plant systems part of the walk-through implements the requirements of Items 3, 4, 7, 8, and 9 of 10 CFR 55.45(a) and encompasses several types of systems, including primary coolant, emergency coolant, decay heat removal, auxiliary, radiation monitoring, and instrumentation and control. ES–301 describes that the control room/in-plant systems part of the walk-through is used to determine whether the applicant has an adequate knowledge of plant system design and is able to safely operate those systems. This part of the walk-through focuses primarily on those systems with which licensed operators are most involved (*i.e.,* those having controls and indications in the main control room). To a lesser extent, it also ensures that the applicant is familiar with the design and operation of systems located outside the main control room.

To evaluate an applicant's knowledge and abilities relative to control room/in-plant systems and competence in the administrative topics, the NRC examiners administer JPMs and, when necessary, ask specific follow-up questions based on the applicant's performance of the JPM. NUREG–1021 defines a JPM as "[a]n evaluation tool that requires the applicant to perform (or simulate) a task that is applicable to the license level of the examination."

Tasks are selected for evaluation in accordance with ES–301, Section D.4, "Specific Instructions for the 'Control Room/In-Plant Systems' Walk-Through." This section directs NRC examiners and facility licensees to select plant systems from the nine safety functions listed in the applicable NRC K/A Catalog. Table 1, "Plant Systems by Safety Function," in NUREG–2103 contains a list of the AP1000 plant systems that are important to each of the nine major safety functions. ES–301, Section D.4.a, directs exam writers to (1) select plant systems from among the nine safety functions and then (2) for each plant system selected, select from either the NRC K/A catalog or the facility licensee's site-specific task list a task for which a JPM exists or can be developed. NUREG–1021, Appendix C, "Job Performance Measure Guidelines," contains Form ES–C–2, "Job Performance Measure Quality Checklist," (*i.e.,* the JPM Checklist), which states that every JPM should, among other things, (1) be supported by the facility's job task analysis (*i.e.,* the JPM must require applicants to perform tasks that are included in the facility licensee's site-specific task list, which is the product of its job task analysis) and (2) be "operationally important." To be "operationally important," the JPM Checklist states that a JPM must meet the threshold criterion of 2.5 in NUREG–2103 (*i.e.,* the K/A statement associated with the JPM must have an importance rating of 2.5 of higher), or as determined by the facility and agreed to by the NRC.

Additionally, ES–301, Section E.2.a, "NRC Examiner Review," directs examiners to independently review each operating test for content, wording, operational validity (*i.e.,* test items address an actual or conceivable mental or psychomotor activity performed on the job), and level of difficulty using Form ES–301–3, "Operating Test Quality Checklist." JPMs must satisfy the criteria on Form ES–301–3 and the JPM Checklist to be administered as part of an operating test.

Per 10 CFR 55.45(b), the operating test will be administered in part in a plant walk-through. Further requirements for the plant walk-through (*i.e.,* the in-plant portion of the operating test) are given in ES–301, Section D.3, "Specific Instructions for the 'Administrative Topics' Walk-through," and Section D.4, "Specific Instructions for the 'Control Room/In-Plant Systems' Walk-Through." Concerning in-plant testing (*i.e.* "plant walk-through"), ES–301, Section D.4.a. states that from the nine safety function groupings identified in the K/A catalog, the appropriate number of systems to be evaluated based on the applicant's license level is given by the following table: [2]

License level	Control room	In-plant	Total
RO	8	3	11
SRO–I	7	3	10
SRO–U	2 or 3	3 or 2	5

In addition, ES–301, Section D.4.a states: "Each of the control room systems and evolutions (and separately each of the in-plant systems and evolutions) selected for RO and SRO–I applicants should evaluate a different safety function, and the same system or evolution should not be used to evaluate more than one safety function in each location."

Also, ES–301, Section D.4.b states, "at least one of the tasks conducted in the plant shall evaluate the applicant's ability to implement actions required during an emergency or abnormal condition, and another shall require the applicant to enter the RCA."

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[2] In the column labeled "License Level," "RO" means "reactor operator" or "operator; "SRO–I" means "senior reactor operator—instant" or "senior operator;" and "SRO–U" means "senior reactor operator—upgrade," and refers to an operator applying to upgrade to a senior operator license.

Taken together, the statements in ES–301, Sections D.4.a and D.4.b show that, for purposes of testing, the control room is separate from the plant. Control room system JPMs are typically performed in the control room simulator. Because plant equipment is not controlled from the simulator, applicants can demonstrate knowledge and abilities by using the simulator to perform the actions necessary to accomplish the task during the JPM. The simulator provides feedback to the applicant about the actions that he or she takes during performance of the task. For example, if the applicant operates a switch to start a pump, the simulator provides indications to the applicant that will allow him or her to determine whether the pump has started.

Administration of In-Plant JPM

Typically, each JPM begins with the NRC examiner providing the applicant with a cue sheet, which contains the cue for the applicant to begin to perform the task. The cue sheet also provides the applicant with any initial conditions that he or she should assume have been established. After receiving the cue sheet, the applicant leads the NRC examiner to the location in the plant where the task will be performed. Once the applicant arrives at the correct location in the plant, he or she uses the appropriate plant procedure and the plant equipment in that location as a prop to describe to the NRC examiner exactly how he or she would perform the task. The task is not actually performed because applicants are not permitted to operate plant equipment while performing a JPM; only licensed control room operators can direct the operation of plant equipment (*i.e.,* an NRC examiner cannot direct the operation of plant equipment). Therefore, as stated in NUREG–1021, ES–301, Attachment 2, Page 21, to successfully complete a JPM in the plant, the applicant must "describe exactly what it takes to perform an action." As described in NUREG–1021, Appendix C, "Job Performance Measure Guidelines," Section B.4, "Develop Examiner Cues," the NRC examiners develop scripted cues to provide the applicant with specific feedback on the equipment's response(s) to actions the applicant describes that he or she would take. These cues are necessary during JPMs performed in the plant because the applicant is not actually operating any equipment in the plant, and therefore the applicant will not have available the normal indications that would be observed during actual task performance.

Consider the following example. An NRC examiner provides the applicant with a cue sheet that directs him or her to start a standby diesel generator from its local control panel, which is located in the plant (*i.e.,* outside of the main control room), for a monthly equipment performance test. The applicant first must demonstrate to the NRC examiner that he or she can locate that particular local control panel in the plant by walking the NRC examiner to it. Once at the local control panel, the applicant must then verbally describe exactly how he or she would operate the control panel to perform the task of starting the standby diesel generator. The applicant will use the local control panel as a prop during this discussion (*e.g.,* the applicant could point to a control switch on the control panel to show the NRC examiner that he or she knows which one must be operated during actual task performance to raise the speed of the diesel generator). The applicant would also need to describe how he or she would expect the standby diesel generator to respond to his or her actions and the indications that he or she would use to monitor whether the standby diesel generator responded as expected. Because the equipment is not actually being operated during an in-plant JPM, the NRC examiner provides specific feedback regarding the equipment's reactions to the actions the applicant says that he or she would take.

If the applicant correctly locates the equipment in the plant and describes what it takes to perform the task, then the applicant will successfully complete the JPM. If the applicant demonstrates a lack of understanding of the equipment and procedures, then the NRC examiner will ask follow-up questions, as necessary, to confirm whether the applicant is familiar with the design and operation of that plant system.

Additionally, at least one JPM must be performed in the RCA. This provides an opportunity for the applicant to demonstrate knowledge of significant radiation hazards located in radiation and/or contamination areas inside the RCA and the ability to perform procedures to reduce excessive levels of radiation and to guard against personnel exposure.

Cold Licensing Process

NUREG–1021, ES–202, Section D.4, "Cold License Eligibility," states, "[c]old licensing is the process used prior to fuel load that provides a consistent method for operations personnel to acquire the knowledge and experience required for licensed operator duties following fuel load." The cold licensing process is described in Appendix A, "Cold License Training Plan," of NEI 06–13A, "Template for an Industry Training Program Description," Revision 2 (ADAMS Accession No. ML090910554). "Final Safety Evaluation for Topical Report NEI 06–13A, 'Template for an Industry Training Program Description,' " Revision 1, dated December 5, 2008 (ADAMS Accession No. ML082950140), documents the NRC staff's approval of NEI 06–13A for use in combined license applications. The facility licensee incorporated NEI 06–13A, Revision 2, in its entirety into the VEGP Units 3 and 4 Updated Final Safety Analysis Report (UFSAR), Chapter 13, "Conduct of Operation" (ADAMS Accession No. ML15194A468). Section 13.2A.3, "Conduct of On-the-Job Training (OJT)," of the VEGP Units 3 and 4 UFSAR states, "[u]ntil plant construction is completed, acceptable methods for the conduct of on-the-job training include discussion, simulation, and use of mockup equipment and virtual reality technology." Section 13.2A.6, "Cold Licensing Process Applicability and Termination," provides additional guidance on the conduct of OJT:

> As plant systems, components, and structures are completed, and as integrated plant operations begin, the systematic approach to training process will be used to adjust cold license class training methods . . . The purpose is to optimize student learning using actual in-plant training and experience opportunities as they become available.

Additionally, Section 13.2A.7, "Initial Licensed Operator Examination Schedule," states, "[a]dministration of [initial] licensed operator examinations begins approximately 18 months prior to fuel load."

II. Request/Action

By letter from Ms. Karen Fili, Site Vice President, VEGP Units 3 and 4, to the NRC dated May 27, 2016, "Southern Nuclear Operating Company Vogtle Electric Generating Plant (VEGP) Units 3 and 4 Revised Request for Exemption and RAI Response: Operator Licensing" ND–16–0747 (ADAMS Accession No. ML16148A484) ("May 27 letter"), the facility licensee stated that it seeks to begin operator licensing examinations in July 2016. The May 27 letter superseded the letter from Ms. Karen Fili, Site Vice President, VEGP Units 3 and 4, to the NRC dated April 15, 2016 (ADAMS Accession No. ML16109A013) (*i.e.,* the April 15 letter). The May 27 letter also incorporated the facility licensee's responses to two requests for additional information (RAIs) issued in response to the April 15 letter: RAI #9 (ADAMS Accession No. ML16112A425) and RAI #10 (ADAMS Accession No. ML16118A183).

The facility licensee (1) applied for exemptions from the requirements in 10 CFR part 55 that require using a plant walk-through as part of the operating test (*i.e.*, in-plant testing); and (2) proposed alternative examination criteria and methods.

Application for Exemption

Because VEGP Unit 3 is under construction and most of the plant systems have not yet been built, the facility licensee requests an exemption from the requirement in 10 CFR 55.45(b) to administer a portion of the operating test "in a plant walkthrough." The facility licensee also requests an exemption from 10 CFR 55.40(a) and (b), which require, in part, the Commission and facility licensees to prepare the operating tests required by 10 CFR 55.45 in accordance with the criteria in NUREG–1021, because ES–301, Section D.4.a and D.4.b require that in-plant system JPMs be performed in the plant (and also that one JPM be performed in the RCA) as part of the walk-through administered to applicants during the operating test. However, with respect to exemptions from 10 CFR 55.40(a) and (b), the Commission determined that none were necessary because the Commission and the facility license would continue to follow NUREG–1021, as required by 10 CFR 55.40(a) and (b), when the Commission and facility licensee used alternative examination criteria pursuant to ES–201, Section B, "Background," of NUREG–1021. The proposed alternative is discussed below.

Proposed Alternative

The facility licensee proposes an alternative to administering in-plant system JPMs in the plant: It proposes to use "cold license training plan evaluation methods" to administer in-plant system JPMs. Specifically, in Enclosure 1, "Plant Walkthrough Exemptions," Section 3.1, "Administration of In-Plant JPMs Using Cold License Training Plan Methods," and Section 3.2, "RCA Mockup Alternative to RCA Entry," of the May 27 letter, the facility licensee proposes using the following "cold license training plan evaluation methods" in lieu of the plant and plant equipment to administer in-plant system JPMs on an operating test:

- Plant layout diagrams,[3] equipment diagrams and plant maps—these documents will be used as necessary and/or as appropriate to allow an applicant to demonstrate knowledge of plant and equipment locations. Applicants will use these tools to describe how they would get to the location of the equipment that is the subject of the JPM and to identify the building, elevation, and room number in the plant where that equipment will be located when construction is complete.
- Breaker Lab—VEGP has a breaker lab that contains 6.9kV and 480V breakers that can be operated by applicants.
- Maintenance Flow Loop—contains generic plant equipment, such as pumps, valves, and instruments for demonstrating the fundamental knowledge of operation and monitoring of plant equipment.
- Remote Shutdown Workstation—The VEGP Units 3 & 4 simulation facility includes a Remote Shutdown Workstation that simulates the controls located in the Remote Shutdown Room.
- RCA mock-up—A training environment that allows applicants to demonstrate knowledge of radiation control subjects. Standards for entry into the mock-up RCA are identical to the actual RCA. The mock-up is used to train outage workers at VEGP Units 1 and 2. It contains simulated radiation areas and contaminated areas.
- Discuss method—using the procedure and props such as plant layout drawings, mock-ups, maps and pictures of equipment, the applicant will describe the actions he or she would take to operate equipment and explain how the equipment should respond to these actions. Discussion can cover required personal protective equipment (PPE), actions, system response and location. Location information can include specifics such as building, elevation, and room.
- Perform method—if the JPM is administered in the breaker lab, the flow loop trainer, or the remote shutdown room mock-up, applicants can perform actions during the JPM as well as discuss.
- Plant location drawings and pictures of plant components not directly related to the task that is the subject of the JPM will also be made available to maintain discriminatory value (*i.e.*, the applicant has the same opportunity to fail as with an in-plant JPM by choosing the incorrect component or by incorrectly simulating the operation of the correct component).

Expiration of Exemptions and Alternative

The facility licensee requested that the exemption expire after the Commission makes its finding in accordance with 10 CFR 52.103(g) ("The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2)") for VEGP Unit 3.

III. Discussion

Granting of Exemption

Pursuant to 10 CFR 55.11, the Commission may, upon application by an interested person, or upon its own initiative, grant exemptions from the requirements of 10 CFR part 55 as it determines are (1) authorized by law and (2) will not endanger life or property and (3) are otherwise in the public interest.

1. The Exemption Is Authorized by Law

Exemptions are authorized by law where they are not expressly prohibited by statute or regulation. A proposed exemption is implicitly "authorized by law" if all of the conditions listed therein are met (*i.e.*, will not endanger life or property and is otherwise in the public interest), and no other provision prohibits, or otherwise restricts, its application. No provisions in law restrict or prohibit an exemption to the requirements concerning the plant walk-through portion of the operating test; the "endanger" and "public interest" factors are addressed later in this evaluation.

The regulations in 10 CFR part 55 implement Section 107 of the Atomic Energy Act of 1954, as amended (AEA), which sets requirements upon the Commission concerning operators' licenses and states, in part, that the Commission shall "prescribe uniform conditions for licensing individuals as operators of any of the various classes of . . . utilization facilities licensed" by the NRC. These requirements in the AEA do not expressly prohibit exemptions to the portion of 10 CFR 55.45(b) addressing in-plant JPMs and plant walk-throughs.

Preparing and evaluating operator examinations using the criteria in NUREG–1021 is a means of ensuring the equitable and consistent administration of operator licensing examinations for all applicants and thus helps to ensure uniform conditions exist for the operator licensing examinations administered as part of the licensing process. If the exemption is granted, there will be no changes to the preparation and grading of the written examinations, including the generic fundamentals examinations. There will be no changes to the preparation and evaluation of the simulator portions of the operating test. There will be no changes to the administrative portion of the operating tests. Although under the exemption part of the in-plant test will not be administered in the plant, the preparation and grading of the in-plant portion will be unchanged.

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[3] A plant layout diagrams typically include building names, building elevations, and room numbers.

Upon balancing the overall effect on uniformity and consistency under the exemption, the NRC staff concludes that the uniform conditions will be maintained; the differences in the testing under the exemption will not prevent equitable administration of the operator licensing examinations or challenge the basis for the NRC examiners' licensing decisions. Accordingly, the testing will continue to comply with Section 107 of the AEA. Accordingly, the NRC staff has determined that granting of the facility licensee's proposed exemption will not result in a violation of the AEA, or the Commission's regulations. Therefore, the exemption is authorized by law.

2. The Exemption Will Not Endanger Life or Property

The exemption will not change the fundamental findings needed to issue an operator's or senior operator's license to an applicant. As stated in 10 CFR 55.33 "Disposition of an initial application,"

> (a) *Requirements for the approval of an initial application.* The Commission will approve an initial application for a license pursuant to the regulations in this part, if it finds that—
>
> . . .
>
> (2) *Written examination and operating test.* The applicant has passed the requisite written examination and operating test in accordance with §§ 55.41 and 55.45 or 55.43 and 55.45. These examinations and tests determine whether the applicant for an operator's license has learned to operate a facility competently and safely, and additionally, in the case of a senior operator, whether the applicant has learned to direct the licensed activities of licensed operators competently and safely.

Competent and safe operators protect against endangerment of life or property. Accordingly, where the tests adequately determine who is competent, those tests are protective of and do not endanger life or property.

The exemption from the requirement in 10 CFR 55.45(b) that the operating test be administered partially "in a plant walkthrough" will not endanger life or property mainly because 10 CFR 55.45(a) will still require the applicant to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a representative sample of tasks. As required by 10 CFR 55.45(a), the content of the operating test will continue to be identified, in part, from learning objectives derived from a systematic analysis of licensed operator or senior operator duties performed by each facility licensee and contained in its training program and from information in the Final Safety Analysis Report, system description manuals and operating procedures, facility license and license amendments, Licensee Event Reports, and other materials requested from the facility licensee by the Commission. Although applicants will not be tested while physically located in front of installed in-plant equipment until the Commission makes its finding in accordance with 52.103(g), the knowledge and abilities applicants must demonstrate to pass the operating test will not change.

Accordingly, there is no endangerment of life or property as a result of the exemption.

3. The Exemption Is Otherwise in the Public Interest

The Commission's values guide the NRC in maintaining certain principles as it carries out regulatory activities. These principles focus the NRC on ensuring safety and security while appropriately balancing the interests of the NRC's stakeholders, including the public and licensees. These principles include Independence, Openness, Efficiency, Clarity, and Reliability. Whether granting of an exemption to the requirement to perform in-plant system JPMs in the plant would be in the public interest depends on consideration and balancing of the foregoing factors.

Efficiency

The public and licensees are all entitled to the best possible management and administration of regulatory activities. Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option that minimizes the use of resources should be adopted.

The NRC staff considered two options to determine whether one would minimize the use of resources and/or minimize risk: (1) Grant the exemption to the plant walk-through requirement and administer operator licensing examinations prior to completion of VEGP Unit 3, or (2) deny the exemption and wait until the completion of construction to administer the operator licensing examinations. For either option, the same number of NRC examiners will be required to administer the operator licensing examinations at VEGP Unit 3 prior to fuel load. Thus, the use of resources is not minimized by administering exams before the plant is built. Accordingly, the exemption is neutral with respect to the public's interest in efficiency.

Clarity

Regulations should be coherent, logical, and practical. There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Here, the goal of the agency is to determine whether applicants for a license have learned to operate a facility competently and safely. Because the applicants must still demonstrate familiarity with the design and operation of systems located outside the main control room using the method proposed by the facility licensee, it is not necessary to perform the in-plant system JPMs within the completed VEGP Unit 3 to achieve this goal. Accordingly, this factor shows that the exemption maintains the public interest in clarity.

Reliability

Regulations should be based on the best available knowledge from research and operational experience. Systems interactions, technological uncertainties, and the diversity of licensees and regulatory activities must all be taken into account so that risks are maintained at an acceptably low level. Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition. Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes.

If a sufficient number of applicants do not pass the exams, then the facility licensee may not have a sufficient number of personnel available for fuel load. If exams commenced in June 2018, and fuel load was scheduled for late 2018, then there would only be at most 6 months between the time when licensing decisions would be made and fuel load. As stated in Enclosure 1, Section 6.3, "Otherwise in the Public Interest," of the May 27 letter, initial license training lasts approximately 24 months; therefore, 6 months is not sufficient to license additional applicants if the needed number of applicants do not pass the examinations. Commencing examinations now allows the facility licensee to better prepare for contingencies and have more assurance that a sufficient number of licensed operators will be available for fuel load. If a sufficient number of applicants do not pass the operating test, the facility licensee can factor the pass/fail decisions into its operational schedules starting in 2016, which will provide a sufficient amount of time for retraining applicants who do not pass the exam or training a new class of applicants. Thus, granting the exemption will lend stability to the nuclear operational and planning process in that the individual operator licensing decisions will be made much sooner than otherwise would be possible.

With respect to risk reduction, granting of the exemption will not require the NRC examiners or the applicants to enter the RCA, and therefore, the risk of radiation exposure for applicants and NRC examiners will be reduced to zero. Although NRC examiners and applicants typically do not receive any significant exposure to radiation or contamination during the conduct of operating tests administered inside the RCA, the NRC staff concludes that reducing the risk of exposure to zero aligns with the agency's goal of maintaining exposure to ionizing radiation as low as is reasonably achievable (ALARA). Accordingly, this factor shows that the exemption favors the public's interest in reliability.

Independence

Nothing but the highest possible standards of ethical performance and professionalism should influence regulation. However, independence does not imply isolation. All available facts and opinions must be sought openly from licensees and other interested members of the public. The many and possibly conflicting public interests involved must be considered. Final decisions must be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated.

With the granting of this exemption, the NRC staff will still continue to independently assess whether the applicants at VEGP Unit 3 have the skills, knowledge, and abilities necessary to operate the plant safely and competently. The operator licensing decisions will continue to be based on the NRC examiners' objective, unbiased assessments of each applicant's performance, which will be documented in accordance with NUREG–1021, ES–303, "Documenting and Grading Initial Operating Tests." Accordingly, this factor shows that the exemption maintains the public interest in independence.

Openness

Nuclear regulation is the public's business, and it must be transacted publicly and candidly. The public must be informed about and have the opportunity to participate in the regulatory processes as required by law. Open channels of communication must be maintained with Congress, other government agencies, licensees, and the public, as well as with the international nuclear community.

Granting the exemption allows the portion of the operating test that would otherwise be performed in the plant to be administered in a location other than the plant. The operator licensing examination process described in NUREG–1021 will still be followed using the alternate method proposed by the facility licensee. Therefore, this factor shows that the exemption maintains the public's interest in openness.

Balancing of Factors

Accordingly, the balancing of these factors shows that the exemption is otherwise in the public interest.

Conclusion

The Commission concludes that the exemption is (1) authorized by law and (2) will not endanger life or property and (3) is otherwise in the public interest. Therefore, the Commission grants SNC an exemption from the requirement of 10 CFR 55.45(b) to administer a portion of the operating test "in a plant walkthrough."

Approval of Alternative

NUREG–1021, ES–201, Section B, "Background," states,

> Facility licensees may propose alternatives to the examination criteria contained here and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The NRC staff will review any proposed alternatives and make a decision regarding their acceptability. The NRC will not approve any alternative that would compromise the agency's statutory responsibility to prescribe uniform conditions for the operator licensing examinations.

As discussed below, the facility licensee's proposed alternatives provide an acceptable method of complying with the Commission's regulations and will not compromise the agency's statutory responsibility to prescribe uniform conditions for the operator licensing examinations.

NUREG–1021, Appendix A, "Overview of Generic Examination Concepts," Section B, "Background," discusses internal and external attributes of an examination and their relationship to uniform conditions. The internal attributes of an examination include its level of knowledge (LOK), level of difficulty (LOD), and the use of exam question banks. The external attributes of an examination include the number and types of items, the length of the examination, security procedures, and proctoring instructions. Appendix A states,

> If the internal and external attributes of examinations are allowed to vary significantly, the uniform conditions that are required by Section 107 of the Atomic Energy Act of 1954, as amended, and the basis upon which the NRC's licensing decisions rest are challenged. The NRC must reasonably control and structure the examination processes to ensure the integrity of the licenses it issues.

In order to determine whether uniform conditions for licensing individuals as operators and senior operators at VEGP Unit 3 will be maintained using the method proposed by the facility licensee, the NRC staff performed two actions. First, the NRC staff identified the differences between performing in-plant system JPMs in the plant and the facility licensee's proposed method of performing in-plant system JPMs. These are listed in the table below.

SUMMARY OF DIFFERENCES

#	Performing in-plant system JPMs in the plant	Facility licensee's proposed method of performing in-plant system JPMs
1	Applicants demonstrate knowledge of equipment locations by walking the NRC examiner to the location of the equipment that is the subject of the JPM in the plant.	In lieu of walking the NRC examiner to the equipment that is the subject of the JPM, applicants demonstrate knowledge of equipment locations by using plant layout diagrams, equipment diagrams, and maps to describe to the NRC examiner how they would get to the location of the plant equipment that is the subject of the JPM. Applicants identify the building, elevation, and room number associated with the plant equipment that is the subject of the JPM.

SUMMARY OF DIFFERENCES—Continued

#	Performing in-plant system JPMs in the plant	Facility licensee's proposed method of performing in-plant system JPMs
2	Applicants use the plant equipment as a prop while they describe and how to operate the equipment to perform the task..	In lieu of using plant equipment as a prop, applicants use pictures of equipment or a mock-up of the equipment as a prop while they describe and simulate how to operate the equipment to perform the task.
3	Applicants must enter the RCA for at least one JPM..	In lieu of entering the RCA in the plant, applicants enter a mock-up RCA for at least one JPM.

Second, the NRC staff evaluated whether the differences could cause the internal and external attributes of the in-plant system JPMs administered to applicants at VEGP Unit 3 prior to the completion of plant construction to vary significantly from those administered to applicants at VEGP Unit 3 after the completion of construction. The evaluation is documented below.

Evaluation of Internal Attributes

Level of Knowledge: As stated in NUREG–1021, Appendix A, Section C.3.c, "Level of Knowledge Versus Level of Difficulty," LOK represents the range of mental demands required to answer a question or perform a task. It is a continuum of mental rigor that ranges from retrieving fundamental knowledge, which is a low LOK, to retrieving that knowledge and also understanding, analyzing, and synthesizing that knowledge with other knowledge, which is a high LOK. Test items that require a high LOK require multiple mental processing steps, which are usually the recall and integration of two or more pieces of data.

In-plant system JPMs performed in the plant are high LOK test items because they require applicants to recall knowledge such as the location of plant equipment, which was acquired during the initial training program, and also to demonstrate, by walking the NRC examiner to the correct equipment in the plant and by describing the actions that they would take to operate the equipment, an understanding of and familiarity with the design and operation of that equipment. Applicants must also respond to the cues provided by the NRC examiner during the JPM. To successfully complete the JPM, the applicant must be able to analyze the information provided by these cues, apply knowledge of the design and operation of the equipment to determine the appropriate action(s), and then describe the action(s) to the NRC examiner.

The NRC staff determined that the three differences listed in Table 2 do not cause the LOK that an applicant at VEGP Unit 3 must demonstrate during in-plant system JPMs administered prior to the completion of plant construction to vary significantly from the LOK that an applicant must demonstrate during in-plant system JPMs performed after the completion of construction at VEGP Unit 3 for the following reasons.

- As shown in Difference #1 in Table 2, the facility licensee proposes that applicants at VEGP Unit 3 demonstrate knowledge of equipment locations by using plant layout diagrams, equipment diagrams, and/or maps to show the NRC examiner how they would get to the location in the plant where the task would be performed. The facility licensee stated in Enclosure 1, "Plant Walkthrough Exemptions," Section 5.5, "Conclusion," of the May 27 letter that the proposed method of performing in-plant system JPMs will "not impact the ability to maintain equitable and consistent testing under uniform conditions because license applicants will be evaluated using the same methods employed during their training." As described in Section 13.2A.1, "Licensed Operator Experience Requirements Prior To Commercial Operation," of the VEGP Units 3 and 4 UFSAR, initial license training for all applicants at VEGP Unit 3 includes a site layout course, which is described in NEI 06–13A, Appendix A as a site familiarization course. Therefore, the NRC staff concludes that this method will require applicants at VEGP Unit 3 to recall and demonstrate knowledge of plant equipment location(s), which were addressed in the training program, to successfully complete the JPM even though the JPM will not be performed in the plant.
- As shown in Difference #2 in Table 2, the facility licensee proposes that applicants at VEGP Unit 3 describe how they will operate the equipment and explain how they expect the equipment and systems to respond to their actions using props such as pictures of the equipment or a mock-up equipment in lieu of the actual equipment in the plant. Just as during a JPM in the plant, NRC examiners will need to provide scripted cues to the applicants in response to the actions the applicants say that they would take. The applicants will have to analyze the information provided by these cues, apply knowledge of the design and operation of the equipment to determine the appropriate action(s), and then describe the action(s) to the NRC examiner. Therefore, the NRC staff concludes that this method will require applicants at VEGP Unit 3 to describe the actions that they would take to operate the equipment and analyze information provided by cues to successfully complete the JPM even though the JPM will not be performed in the plant.
- As shown in Difference #3 in Table 2, applicants at VEGP Unit 3 will be required to demonstrate how to enter the RCA. The facility licensee has established a mock-up of the RCA that contains simulated radiation control areas and contaminated areas, and "standards for entry into the mockup RCA are identical to an actual RCA." Therefore, the NRC staff concludes that this method will require applicants at VEGP Unit 3 to demonstrate knowledge of significant radiation hazards located in radiation and/or contamination areas inside the RCA and the ability to perform procedures to reduce excessive levels of radiation and to guard against personnel exposure even though the JPM will not be performed in the plant.

Accordingly, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs will not cause the LOK of the in-plant system JPMs administered to applicants at VEGP Unit 3 prior to the completion of plant construction to vary significantly from those administered to applicants at VEGP Unit 3 after the completion of construction.

Level of Difficulty: As stated in NUREG–1021, Appendix A, Section C.3.c, "Level of Knowledge Versus Level of Difficulty," the NRC examiners evaluate a test item's LOD "to ensure that the item can help discriminate between safe and unsafe operators." "Safe operators" are the applicants who pass all portions of the operator licensing examination with a score of 80% or higher. Thus, NUREG–1021 recommends that the difficulty for individual test items range between 70% and 90% (*i.e.,* 70–90% of applicants could successfully perform the test item). To achieve this, NUREG–1021 states that the NRC examiners must integrate the following concepts:

The LOK of the test item, the operational validity of the test item (*i.e.*, the test item requires applicants to perform mental or psychomotor activities that they will have to perform on the job), the ability of distractors to distract the examinees, and the examinees' past performance on items of similar difficulty. Appendix A acknowledges that "assigning a level of difficulty rating to an individual test item is a somewhat subjective process."

The NRC staff determined that the three differences listed in Table 2 do not cause the LOD that an applicant at VEGP Unit 3 must demonstrate during in-plant system JPMs administered prior to the completion of plant construction to vary significantly from the LOD that an applicant must demonstrate during in-plant system JPMs performed after the completion of construction at VEGP Unit 3 for the following reasons.

- As shown in Difference #1 in Table 2, the facility licensee proposes that applicants at VEGP Unit 3 demonstrate knowledge of equipment locations by using plant layout diagrams, equipment diagrams, and/or maps to (1) to describe to the NRC examiner how they would get to the location of the plant equipment that is the subject of the JPM and to (2) correctly identify the building, elevation of the building, and room number where the equipment will be located in VEGP Unit 3. Additionally, the facility licensee proposes that "plant layout diagrams and/or pictures of components not directly related to the task will also be made available to the applicant to maintain discriminatory value . . ."

When an in-plant system JPM is performed in the plant, applicants must physically walk the NRC examiner to the correct location in the plant where the task will be performed. Applicants must choose the correct location from among all of the other accessible plant locations. Similarly, applicants at VEGP Unit 3 must choose the correct plant layout diagram(s), equipment diagrams and/or map(s) from a set of diagrams in order to show the NRC examiner how they would locate the equipment in the plant.

If an applicant at an operating reactor has spent a sufficient amount of time in the plant becoming familiar with its layout and the location of plant equipment, then walking the NRC examiner to the correct location during a JPM in the plant will be a relatively easy task. Otherwise, this will be a relatively difficult task, and the applicant may not be able to perform if he or she cannot find the equipment that is the subject of the JPM. Similarly, if an applicant at VEGP Unit 3 has spent a sufficient amount of time becoming familiar with the plant layout diagrams and maps, then using these tools to show the NRC examiner how he or she would access the equipment will be a relatively easy task. Otherwise, this will be a relatively difficult task, and the applicant may not be able to continue with the JPM because he or she will not successfully demonstrate the ability to access the equipment. In both cases, the applicants will either be able to demonstrate knowledge to the NRC examiner, or they will not be able to demonstrate knowledge. The NRC staff concludes that both methods require applicants to select the correct location of plant equipment from among other choices, and therefore the NRC examiners will still be able to discriminate between operators that have this knowledge and those that do not, and thus the LOD of the two methods is comparable.

Also, the NRC staff considered the implications for the testing process of physically walking in the plant to a specific location as compared to using plant layout diagrams and/or maps to show and describe the route that would be taken to find the correct location impacted LOD. Both methods require an applicant to recall and show knowledge of plant locations to the NRC examiner. However, applicants at plants that have been constructed will have spent time becoming familiar with the routes through the plant that they must take to access equipment during the conduct of OJT in the plant. During an in-plant system JPM in the plant, they will likely be able to recall the route(s) they have previously traveled by relying on unique visual clues available in the plant such as signage and various access control points that they must pass through to navigate their path to the equipment that is the subject of the JPM. They may also possibly rely on muscle memory to some extent to locate the equipment that is the subject of the JPM. Additionally, NUREG–1021, Appendix E, "Policies and Guidelines for Taking NRC Examinations," contains directions that NRC examiners provide to applicants and licensed operators prior to every NRC examination. Appendix E, Section C.3, states,

> The operating test is considered "open reference." The reference materials that are normally available to operators in the facility and control room (including calibration curves, previous log entries, piping and instrumentation diagrams, calculation sheets, and procedures) are also available to you during the operating test.

Plant layout diagrams and site maps are normally available to operators. Thus, applicants at plants that have been constructed may use plant layout diagrams and site maps to help them to locate the equipment that is the subject of the JPM if they cannot recall the location of the equipment from memory.

Unlike applicants at plants that have been constructed, the applicants at VEGP Unit 3 that take operator licensing examinations prior to the completion of plant construction will only use plant layout diagrams and maps to describe the route they would take to access the plant equipment. This method requires applicants to stand in front of a document and trace or identify the route that would be taken. This method is different from actually walking to a location in the plant because (1) visual clues that would be available to applicants in the plant will not be available, and (2) this method requires applicants to use fewer motor skills, and thus it is not likely that applicants will be able to use any muscle memory. This may increase the LOD. However, Section 13.2A.1, "Licensed Operator Experience Requirements Prior To Commercial Operation," of the VEGP Units 3 and 4 UFSAR states that all applicants at VEGP Unit 3 must complete a site layout course. Also, the facility licensee stated in Enclosure 1, "Plant Walkthrough Exemptions," Section 5.5, "Conclusion," of the May 27 letter that the proposed method of performing in-plant system JPMs will "not impact the ability to maintain equitable and consistent testing under uniform conditions because license applicants will be evaluated using the same methods employed during their training." The NRC staff concludes that any increase in LOD as a result of only using plant layout diagrams and maps to demonstrate knowledge of locations will be offset by the fact that the applicants will have been specifically trained on the locations of plant equipment with these tools.

- As shown in Difference #2 in Table 2, applicants will use pictures of equipment or a mock-up of the equipment as a prop while they describe and simulate how to operate the equipment to perform the task. Instead of pointing to a piece of equipment in the plant and verbally describing how to operate it, the applicant will either point to a diagram or picture of the equipment as a prop while describing how to operate it or use a piece of mock-up equipment to actually perform the task required by the JPM. The facility licensee proposes that diagrams and pictures of components not directly related to the task will also be made available to the applicant so that the applicant must make a choice. The NRC staff determined that the facility licensee's proposed method of performing in-plant system JPMs will require an applicant to select the correct piece of equipment from among other options, which is similar to having to make that selection in the plant. Therefore, the NRC examiners will still be able to discriminate between operators that have this knowledge and those that do not, and thus the LOD of the two methods is comparable.

The NRC staff also considered the difference in the quality of the props used in the facility licensee's proposed method of performing in-plant system JPMs compared to the quality of the plant equipment as a prop. Enclosure 2, "Response to NRC Request for Additional Information No.9," contains Table E2–1, which lists tasks from the VEGP Units 3 and 4 site-specific task list that could be a JPM. The NRC staff reviewed Table E2–1 and determined that the breaker lab, the maintenance flow loop trainer, the RCA mock-up, and the Remote Shutdown Workstation available in the VEGP training facilities could be used as props during some JPMs. These tools are realistic representations of certain pieces of plant equipment and are therefore equivalent to the actual plant equipment.

However, these tools will not be able to be used for every in-plant system JPM that could be developed because the tasks listed in Table E2–1 include tasks unrelated to breaker operation, remote shutdown, or plant components modeled in the flow loop trainer (*e.g.*, Table E2–1 includes a task to "startup the in core instrument system"). In these instances, the facility licensee proposes to use equipment diagrams or pictures of plant equipment as props. In these cases, the pictures may not be the same size as the actual plant equipment, or, in the case of equipment diagrams, they might not provide the same visual detail to an applicant that would be provided by the actual plant equipment. This could make these props more difficult to use compared to the actual plant equipment. However, because the facility licensee proposes to use the same props during the administration of in-plant system JPMs that have been used in the training program, the NRC staff concludes that any increase in LOD as a result of using pictures or equipment diagrams to demonstrate knowledge will be offset by the fact that the applicants have used these props during their training.

- As shown in Difference #3 in Table 2, applicants will have to enter a mock-up of the RCA for at least one in-plant JPM. As stated in the facility licensee's submittal, the "standards for entry into the mockup RCA are identical to an actual RCA." Therefore, the NRC staff concludes that this difference has no impact on the LOD of the in-plant system JPMs because there is no difference between demonstrating the ability to enter the actual RCA and demonstrating the ability to enter a mock-up of the RCA.

Accordingly, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs will not cause the LOD of the in-plant system JPMs administered to applicants at VEGP Unit 3 prior to the completion of plant construction to vary significantly from those administered to applicants at VEGP Unit 3 after the completion of construction.

Use of Exam Banks: NUREG–1021, Form ES–301–2, "Control Room/In-Plant Systems Outline," contains criteria for the use of JPMs in the facility licensee's exam bank that may be used on operator licensing examinations. In Enclosure 1, "Plant Walkthrough Exemptions," Section 5.3, "Discrimination Validity," the facility licensee stated, "[a]ny questions, discussions, or other cold licensing methods used for task evaluation will have no impact on how the examination bank is used." The NRC staff also concluded that the facility licensee's proposed method of performing in-plant system JPMs does not impact the use of exam banks because the facility licensee's proposed method of administering JPMs has nothing to do with the selection of JPMs from its exam bank.

In summary, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs does not significantly impact the internal attributes of the in-plant system JPMs that will be administered to applicants at VEGP Unit 3 prior to the completion of plant construction as compared to the in-plant system JPMs administered to applicants at plants that have been constructed.

Evaluation of External Attributes

The external attributes of an examination include the number and types of items (*e.g.*, in-plant system JPMs), the length of the examination, security procedures, and proctoring instructions. The facility licensee is not proposing to alter the number or types of items, the length of the examination, security procedures, or proctoring instructions for any part of the operator licensing examination. Therefore, the NRC staff concludes that the external attributes of the operator licensing examinations that will be administered to applicants at VEGP Unit 3 prior to the completion of plant construction will be the same external attributes of the operator licensing examinations administered to applicants at plants that have been constructed.

Summary of Evaluation of Internal and External Attributes

In summary, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs does not cause the internal and external attributes of the in-plant system JPMs administered to applicants at VEGP Unit 3 prior to the completion of plant construction to vary significantly from those administered to applicants at VEGP Unit 3 after the completion of construction. Because in-plant system JPMs are a portion of the operator licensing examination, the NRC staff also concludes that the facility licensee's proposed method does not cause the internal or external attributes of the operator licensing examinations that will be administered to applicants at VEGP Unit 3 prior to the completion of plant construction to vary significantly from those administered to applicants at VEGP Unit 3 after the completion of construction.

Impact of Plant Construction on Developing Content-Valid Exams

In Enclosure 2, "Response to NRC Request for Additional Information No. 9" of the May 27 letter, the facility licensee stated that some in-plant tasks on the site-specific task list that have an importance rating of 2.5 or higher cannot be used to develop a JPM at this time. Because not all plant systems have been constructed or turned over to the facility licensee from the vendor, some procedures are not available at this time. A JPM cannot be performed without a procedure. If the pool of in-plant tasks that could be used to develop a JPM is limited, then it is possible that important K/As could be omitted from the operating test, which would reduce the content validity of the exam.

In Enclosure 2 of the May 27 letter, the facility licensee provided Table E2–1. Of the tasks that the facility licensee included in Table E2–1, the NRC staff found that 101 of 109 possible tasks have procedures available at this time and therefore can be used to develop an in-plant system JPM; only eight tasks do not have procedures available at this time and thus cannot be used to develop an in-plant system JPM. Of these eight tasks, the NRC staff compared the safety functions listed for each of the eight tasks with the safety functions listed in Table 1, "Plant Systems by Safety Function," in NUREG–2103. The NRC staff found that of the eight tasks, two are associated with plant systems related to Safety Function #6, Electrical; five are associated with plant service systems related to Safety Function #8, Plant Service Systems; and one is associated with a plant system related to Safety Function #4, Heat Removal from the Reactor Core.

The NRC staff reviewed the 101 tasks that do have procedures available at this time and found that multiple tasks associated with the plant systems related to these safety functions as well as the other safety functions listed in Table 1 in NUREG–2103 can be used at this time to develop an in-plant system JPM. Thus, although these eight tasks may be excluded from the sample at this time, there is still a diverse set of other tasks that can be used to test an applicant's knowledge and abilities related to the operation of plant systems associated with each of the nine safety functions. Additionally, because the plant systems associated with Safety Functions #4, 6, and 8 are primarily operated from the main control room, the criteria in NUREG–1021, ES–301, Section D.4.a, which states that "each of the control room systems and evolutions (and separately each of the in-plant systems and evolutions) selected . . . should evaluate a different safety function . . .," will still be followed, thus ensuring that the content of each operating test sufficiently samples the safety functions and K/As. Thus, the NRC staff concludes that the elimination of these eight tasks from the possible pool of in-plant system JPMs at this time does not result in any omission of K/As from the operator licensing examinations administered to applicants at VEGP Unit 3 at this time. Therefore, the examinations administered to applicants at VEGP Unit 3 at this time will be content-valid examinations.

Impact of Alternative Method on Knowledge Retention and Learning New Knowledge

The NRC staff has assurance that all applicants who become licensed at VEGP Unit 3 will be trained and tested on new procedures and tasks as they become available. This is because all licensed operators are subject to the requalification requirements of 10 CFR 55.59. These requirements include additional operating tests as follows:

> (a) *Requalification requirements.* Each licensee shall—
>
> (1) Successfully complete a requalification program developed by the facility licensee that has been approved by the Commission. This program shall be conducted for a continuous period not to exceed 24 months in duration.
>
> (2) Pass a comprehensive requalification written examination and an annual operating test.
>
> (i) The written examination will sample the items specified in §§ 55.41 and 55.43 of this part, to the extent applicable to the facility, the licensee, and any limitation of the license under § 55.53(c) of this part.
>
> (ii) The operating test will require the operator or senior operator to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a comprehensive sample of items specified in § 55.45(a) (2) through (13) inclusive to the extent applicable to the facility.

In other words, the applicants who receive a license will be required to take additional operating tests to maintain the license as part of the licensed operator requalification program. Therefore, the requalification program gives the NRC staff additional confidence that, as the plant is completed, operators will be continually trained and tested on operationally-important in-plant systems and tasks directed by procedures that have not been developed yet.

NUREG–1021 provides guidance for applicants transitioning from the initial license program to the requalification program: ES–605, Section C.1.b, states, "Newly licensed operators must enter the requalification training and examination program promptly upon receiving their licenses." Also, ES–204 states that the region may administer a license examination to an applicant who has not satisfied the applicable training or experience requirements at the time of the examination, but is expected to complete them shortly thereafter. These requirements in NUREG–1021 help to ensure that the period of time between completing all of the requirements to be licensed, which includes completing the initial license training program and passing the operator licensing examination, and entering a requalification program that meets the requirements of 10 CFR 55.59 is minimized so that applicants (1) receive refresher training on topics learned in the initial training program, which ensures knowledge retention of operationally-important topics, and (2) receive training on new operationally-important topics as they become available (*e.g.*, new procedures and tasks).

In Enclosure 1, "Plant Walkthrough Exemptions," Section 6.3, "Otherwise in the Public Interest," of the May 27 letter, the facility licensee stated that applicants "enrolled in an initial license training (ILT) program are training as a full-time job and cannot participate in completing the required 6 months of meaningful work experience." As described in NEI 06–13A, Appendix A, applicants in the cold licensing process must complete at least 6 months of "practical and meaningful work experience" as part of the experience requirements for an operator's license. Applicants that do not complete any of a portion of the 6 months of practical and meaningful work assignments prior to enrolling in the ILT program will have to do so before the NRC issues a license. Therefore, some applicants at VEGP Unit 3 may not complete the requirements to be licensed "shortly" after taking the operator licensing examination. Because these applicants would not yet be licensed, under NRC regulations they would not be required to be enrolled in a training program that meets the requirements of 10 CFR 55.59, "Requalification."

Although these applicants will be participating in practical and meaningful work assignments to gain experience with the AP1000 design, these assignments do not necessarily ensure that these applicants will receive refresher training on topics learned in the ILT program or receive training on new topics as they become available. In accordance with 10 CFR 55.51,

> If the Commission determines that an applicant for an operator license or a senior operator license meets the requirements of the Act and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary.

Therefore, the Commission may find it necessary to issue licenses with any conditions or limitations that may be necessary to ensure that the applicants have retained knowledge and learned new operationally-important topics during the time between completion of the operator licensing examination and issuance of the license.

In summary, as allowed by NUREG–1021, ES–201, Section B, "Background," with its exemption request, the facility licensee proposed alternatives to the examination criteria contained in NUREG–1021 with respect to the in-plant/plant walk-through portions of the operating test. The NRC staff reviewed the proposed method of administering in-plant system JPMs described in Enclosure 1 of the May 27 letter. For the reasons described above, the NRC staff concluded that the proposed alternatives provide an acceptable method of complying with the Commission's regulations, as exempted.

If, in the future, the facility licensee desires to implement an approach that differs from the alternative described in the May 27 letter, then it should seek approval from the NRC.

Limitations and Expiration

The facility licensee requested the exemption from the regulation that requires the operating test to be administered in a plant walk-through because of the incomplete construction of the plant. As construction of different sections of the facility becomes substantially complete and in-plant systems, components, and structures (SSCs) near completion, usage of this exemption will become unnecessary for those areas and SSCs. Accordingly, on a case-by-case basis, for those tasks that are selected to be part of an operating task in accordance with NUREG–1021, ES–301, Section D.4.a and Section D.4.b, where it is possible to both perform on-the-job training in the plant and administer part of an operating test in a plant walk-through, as determined by the NRC examiners, this exemption may not be used. Furthermore, this exemption will finally expire and may no longer be used upon the Commission's finding for VEGP Unit 3 in accordance with 10 CFR 52.103(g) ("The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2).").

Environmental Consideration

This exemption allows one, two, or three of the required in-plant system JPMs to be performed using discussion and performance methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups in lieu of plant equipment. The NRC staff evaluated whether there would be significant environmental impacts associated with the issuance of the requested exemptions. The NRC staff determined the proposed action fits a category of actions that do not require an environmental assessment or environmental impact statement.

For the following reasons, this exemption meets the eligibility criteria of 10 CFR 51.22(c)(25) for a categorical exclusion. There is no significant hazards consideration related to this exemption. The NRC staff has also determined that the exemption involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite; that there is no significant increase in individual or cumulative public or occupational radiation exposure; that there is no significant construction impact; and that there is no significant increase in the potential for or consequences from radiological accidents. Finally, the requirements to which the exemption applies involve qualification requirements. Accordingly, the exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(25). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the exemption.

IV. Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 55.11, issuing this exemption from the requirement in 55.45(b) to administer a portion of the operating test in a plant walk-through is authorized by law and will not endanger life or property and is otherwise in the public interest. The Commission also has approved the facility licensee's proposed alternative to the examination criteria in NUREG–1021, ES–301, Section D.4.a and Section D.4.b and therefore will allow one, two, or three of the required in-plant system JPMs to be performed using discussion and performance methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups in lieu of plant equipment until the Commission makes a finding for VEGP Unit 3 that acceptance criteria in the combined license are met in accordance with 10 CFR 52.103(g).

Dated at Rockville, Maryland, this 24th day of June, 2016.

For the Nuclear Regulatory Commission.

Samuel S. Lee,

Acting Deputy Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–15547 Filed 6–29–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–369 and 50–370; NRC–2016–0128]

Duke Energy Carolinas, LLC and North Carolina Electric Membership Corporation; Acceptance Criteria for Emergency Core Cooling Systems, McGuire Nuclear Station, Units 1 and 2, Catawba Nuclear Station, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a license amendment request and exemption request dated August 20, 2015, from Duke Energy Carolinas, LLC (Duke Energy or the licensee) from portions of the regulations to support the use of fuel that is clad in Optimized ZIRLO™.

ADDRESSES: Please refer to Docket ID NRC–2016–0128 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0128. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: G. Edward Miller, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–2481, email *Ed.Miller@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Duke Energy is the holder of Facility Operating License Nos. NPF–9, NPF–17, NPF–35, and NPF–52, which authorize operation of the McGuire Nuclear Station (MNS), Units 1 and 2, and Catawba Nuclear Station (CNS), Units 1 and 2. The licenses provide, among other things, that each facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect.

The MNS and CNS units are pressurized-water reactor located in Mecklenburg County, North Carolina, and York County, South Carolina, respectively.

II. Request/Action

Pursuant to section 50.12 of title 10 of the *Code of Federal Regulations* (10

CFR), "Specific Exemptions," the licensee has, by letter dated August 20, 2015 (ADAMS Accession No. ML15295A016), requested an exemption from 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems [ECCS] for light-water nuclear power reactors," and appendix K to 10 CFR part 50, "ECCS Evaluation Models" to allow the use of fuel rods clad with Optimized ZIRLO™. Section 50.46 requires that the calculated cooling performance following postulated loss-of-coolant accidents at reactors fueled with zircaloy or ZIRLO® cladding conforms to the criteria set forth in paragraph (b) of that section. In addition, appendix K to 10 CFR part 50, in part, requires that the Baker-Just equation be used to predict the rates of energy release, hydrogen concentration, and cladding oxidation from the metal/water reaction. The Baker-Just equation assumes the use of zircaloy or ZIRLO®, materials that have different chemical compositions from Optimized ZIRLO™. As written, these regulations presume only the use of zircaloy or ZIRLO® fuel rod cladding and do not contain provisions for use of fuel rods with other cladding materials. Therefore, an exemption from the requirements of 10 CFR 50.46 and part 50, appendix K, is needed to support the use of a different fuel rod cladding material. Accordingly, the licensee requested an exemption that would allow the use of Optimized ZIRLO™ fuel rod cladding at MNS and CNS.

III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, when the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security. However, § 50.12(a)(2) states that the Commission will not consider granting an exemption unless special circumstances are present as set forth in § 50.12(a)(2). Under 10 CFR 50.12(a)(2)(ii), special circumstances are present when application of the regulation in the particular circumstances would not serve, or is not necessary to achieve, the underlying purpose of the rule.

Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.46 and appendix K to 10 CFR part 50 is to establish acceptance criteria for ECCS performance to provide reassurance of safety in the event of a loss-of-coolant (LOCA) accident. Although the wording of the regulations in 10 CFR 50.46 and appendix K is not expressly applicable to Optimized ZIRLO™, the evaluations described in the following sections of this exemption show that the purpose of the regulations are met by this exemption in that, subject to certain conditions, the acceptance criteria are valid for Optimized ZIRLO™ fuel cladding material, Optimized ZIRLO™ would maintain better post-quench ductility, and the Baker-Just equation conservatively bounds LOCA scenario metal-water reaction rates and is applicable to Optimized ZIRLO™. Because the underlying purposes of 10 CFR 50.46 and appendix K can be achieved through the application of these requirements to the use of Optimized ZIRLO™ fuel rod cladding material, the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of an exemption exist.

The Exemption Is Authorized by Law

This exemption would allow the use of fuel rods clad with Optimized ZIRLO™ in future core reload applications for MNS and CNS. Section 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR part 50 provided that the exemptions are authorized by law. The NRC staff determined that special circumstances exist to grant the proposed exemption and that granting the exemption would not result in a violation of the Atomic Energy Act of 1954, as amended. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The provisions of 10 CFR 50.46 establish acceptance criteria for ECCS performance. Westinghouse topical reports WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, "Optimized ZIRLO™," dated July 2006, contain the justification to use Optimized ZIRLO™ fuel rod cladding material in addition to Zircaloy-4 and ZIRLO®. The complete topical reports are not publicly available because they contain proprietary information, however, a redacted version and the NRC safety evaluation are available under ADAMS Accession No. ML062080569. The NRC staff found that the Westinghouse topical reports demonstrated the applicability of these ECCS acceptance criteria to Optimized ZIRLO™, subject to the compliance with the specific conditions of approval established therein. The NRC staff reviewed the August 20, 2015, application against these specific conditions and found that the licensee was in compliance with all of the applicable conditions. The NRC staff's review of these specific conditions for MNS and CNS can be found under ADAMS Accession No. ML16105A326.

Ring compression tests performed by Westinghouse on Optimized ZIRLO™ were reviewed and approved by the NRC staff in topical report WCAP–14342–A & CENPD–404–NP–A, Addendum 1–A, and demonstrate an acceptable retention of post-quench ductility up to the 10 CFR 50.46 limits of 2,200 degrees Fahrenheit and 17 percent equivalent clad reacted. Furthermore, the NRC staff has concluded that oxidation measurements provided by Westinghouse illustrate that oxide thickness (and associated hydrogen pickup) for Optimized ZIRLO™ at any given burnup would be less than that for both zircaloy and ZIRLO™ (ADAMS Package Accession No. ML073130555). Hence, the NRC staff concludes that Optimized ZIRLO™ would be expected to maintain acceptable post-quench ductility.

The provisions of 10 CFR part 50, appendix K, paragraph I.A.5, "Metal-Water Reaction Rate," serve to ensure that cladding oxidation and hydrogen generation are limited appropriately during a loss-of-coolant accident (LOCA) and conservatively accounted for in the ECCS evaluation model. That regulation requires that the Baker-Just equation be used in the ECCS evaluation model to determine the rate of energy release, cladding oxidation, and hydrogen generation. Since the use of the Baker-Just equation presumes the use of zircaloy-clad fuel, strict application of the rule would not permit use of the equation for Optimized ZIRLO™ cladding for determining acceptable fuel performance. As concluded in the NRC staff safety evaluation for the associated topical report, Westinghouse demonstrated that the Baker-Just model is conservative in all post-LOCA scenarios with respect to the use of the Optimized ZIRLO™ as a fuel cladding material.

The NRC-approved topical reports have demonstrated that predicted chemical, thermal, and mechanical characteristics of the Optimized ZIRLO™ alloy cladding are bounded by those approved for ZIRLO® under anticipated operational occurrences and postulated accidents. Reload cores are required to be operated in accordance with the operating limits specified in the technical specifications and the core operating limits report.

Based on the above, no new accident precursors are created by using Optimized ZIRLO™; thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety due to using Optimized ZIRLO™.

Consistent With Common Defense and Security

The proposed exemption would allow the use of Optimized ZIRLO™ fuel rod cladding material at MNS and CNS. This change to the plant configuration is adequately controlled by TS requirements and is not related to security issues. Because the common defense and security is not impacted by this exemption, the exemption is consistent with the common defense and security.

Environmental Considerations

The NRC staff determined that the exemption discussed herein meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9) because it is related to a requirement concerning the installation or use of a facility component located within the restricted area, as defined in 10 CFR part 20, and issuance of this exemption involves: (i) No significant hazards consideration, (ii) no significant change in the types or a significant increase in the amounts of any effluents that may be released offsite, and (iii) no significant increase in individual or cumulative occupational radiation exposure. Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's consideration of this exemption request. The basis for the NRC staff's determination is discussed as follows with an evaluation against each of the requirements in 10 CFR 51.22(c)(9)(i)–(iii).

Requirements in 10 CFR 51.22(c)(9)(i)

The NRC staff evaluated whether the exemption involves no significant hazards consideration using the standards described in 10 CFR 50.92(c), as presented below:

1. Does the proposed exemption involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS changes add flexibility in the selection of fuel rod cladding materials for use at CNS and MNS. The proposed change of adding a cladding material does not result in an increase to the probability or consequences of an accident previously evaluated. TS 4.2.1 addresses the fuel assembly design, and currently specifies that, "Each assembly shall consist of a matrix of either ZIRLO® or Zircaloy fuel rods . . ." The proposed change will add Optimized ZIRLO™ to the approved fuel rod cladding materials listed in this TS. In addition, a reference to the Westinghouse VANTAGE+ fuel assembly core reference report, WCAP–12610–P–A, and the topical report for Optimized ZIRLO™, WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, will be included in the listing of approved methods used to determine the core operating limits for CNS and MNS given in TS 5.6.5.b. Westinghouse topical report WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, Optimized ZIRLO™, provides the details and results of material testing of Optimized ZIRLO™ compared to standard ZIRLO®, as well as the material properties to be used in various models and methodologies when analyzing Optimized ZIRLO™. As the nuclear industry pursues longer operating cycles with increased fuel discharge burnup and fuel duty, the corrosion performance requirements for the nuclear fuel cladding become more demanding. Optimized ZIRLO™ was developed to meet these industry needs by providing a reduced corrosion rate while maintaining the composition and physical properties, such as mechanical strength, similar to standard ZIRLO®. Fuel rod internal pressure has also become more limiting due to changes such as increased fuel duty and use of integral fuel burnable absorbers. Reducing the associated corrosion buildup by using Optimized ZIRLO™ in turn reduces temperature feedback effects, providing additional margin to the fuel rod internal pressure design criterion. Fuel with Optimized ZIRLO™ cladding will continue to satisfy the pertinent design basis operating limits, so cladding integrity is maintained. There are no changes that will adversely affect the ability of existing components and systems to mitigate the consequences of any accident. Therefore, addition of Optimized ZIRLO™ to the allowable cladding materials for CNS and MNS does not result in an increase in the probability or consequences of an accident previously evaluated.

The NRC has previously approved use of Optimized ZIRLO™ fuel cladding material in Westinghouse fueled reactors provided that licensees ensure compliance with the Conditions and Limitations set forth in the NRC Safety Evaluation for the topical report. Confirmation that these Conditions are satisfied is performed as part of the normal core reload process.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed exemption create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed TS changes add flexibility in the selection of fuel rod cladding materials for use at CNS and MNS. Optimized ZIRLO™ was developed to provide a reduced cladding corrosion rate while maintaining the benefits of mechanical strength and resistance to accelerated corrosion from potential abnormal chemistry conditions. The fuel rod design bases are established to satisfy the general and specific safety criteria addressed in the CNS and MNS UFSAR [Updated Final Safety Analysis Report], Chapter 15 (Accident Analyses). The fuel rods are designed to prevent excessive fuel temperatures, excessive fuel rod internal gas pressures due to fission gas releases, and excessive cladding stresses and strains. Westinghouse topical report WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, Optimized ZIRLO™, provides the details and results of material testing of Optimized ZIRLO™ compared to standard ZIRLO®, as well as the material properties to be used in various models and methodologies when analyzing Optimized ZIRLO™. The original fuel design basis requirements have been maintained. No new single failure mechanisms will be created, and there are no alterations to plant equipment or procedures that would introduce any new or unique operational modes or accident precursors. Therefore, addition of another approved cladding material of similar composition and properties as the current approved cladding materials to the CNS and MNS TS does not create the possibility of a new or different kind of accident or malfunction from those previously evaluated within the UFSAR.

3. Does the proposed exemption involve a significant reduction in a margin of safety?

Response: No.

The proposed change will not involve a significant reduction in the margin of safety because it has been demonstrated that the material properties of the Optimized ZIRLO™ are not significantly different from those of standard ZIRLO®. Optimized ZIRLO™ is expected to perform similarly to standard ZIRLO® for all normal operating and accident scenarios, including both loss of coolant accident (LOCA) and non-LOCA scenarios. For LOCA scenarios, where the slight difference in Optimized ZIRLO™ material properties relative to standard ZIRLO® could have some impact on the overall accident scenario, plant-specific LOCA analyses using Optimized ZIRLO™ properties demonstrates that the acceptance criteria of 10 CFR 50.46 has been satisfied, therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, the NRC staff concludes that the proposed exemption involves no significant hazards consideration. Accordingly, the requirements of 10 CFR 51.22(c)(9)(i) are met.

Requirements in 10 CFR 51.22(c)(9)(ii)

The proposed exemption would allow the use of Optimized ZIRLO™ fuel rod cladding material in the reactors. Optimized ZIRLO™ has essentially the same material properties and performance characteristics as the currently licensed ZIRLO® cladding. Thus, the use of Optimized ZIRLO™ fuel rod cladding material will not significantly change the types of effluents that may be released offsite, or significantly increase the amount of effluents that may be released offsite. Therefore, the requirements of 10 CFR 51.22(c)(9)(ii) are met.

Requirements in 10 CFR 51.22(c)(9)(iii)

The proposed exemption would allow the use of Optimized ZIRLO™ fuel rod cladding material in the reactors. Optimized ZIRLO™ has essentially the same material properties and performance characteristics as the currently licensed ZIRLO® cladding. Thus, the use of Optimized ZIRLO™ fuel rod cladding material will not significantly increase individual occupational radiation exposure, or significantly increase cumulative occupational radiation exposure. Therefore, the requirements of 10 CFR 51.22(c)(9)(iii) are met.

IV. Conclusions

Accordingly, the Commission has determined that pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, is consistent with the common defense and security, and that special circumstances are present to warrant issuance of the exemption. Therefore, the Commission hereby grants Duke Energy an exemption from the requirements of 10 CFR 50.46 and Appendix K, paragraph I.A.5 to 10 CFR part 50, to allow the application of these criteria to, and the use of, Optimized ZIRLO™ fuel rod cladding material at MNS and CNS.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 21st day of June 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–15548 Filed 6–29–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting

DATE: June 28, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of June 27, 2016

Wednesday, June 29, 2016

9:55 a.m. Affirmation Session (Public Meeting) (Tentative)

Strata Energy Inc. (Ross in Situ Uranium Recovery Project)—Joint Intervenors' Petition for Review of Initial Decision, LBP–15–3, and Related Interlocutory Decisions. (Tentative)

* * * * *

ADDITIONAL INFORMATION: By a vote of 4–0 on June 27, 2016, the Commission determined pursuant to U.S.C. 552b(e) and 9.107(a) of the Commission's rules that the item in the above referenced Affirmation Session be held with less than one week notice to the public. The meeting is scheduled on June 29, 2016.

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: June 28, 2016.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–15650 Filed 6–28–16; 11:15 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Reemployment of Annuitants

AGENCY: U.S. Office of Personnel Management.

ACTION: 30-Day Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), the Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an existing information collection request (ICR) 3206–0211, Reemployment of Annuitants. Notice of the information collection was previously published in the **Federal Register** *[Vol. 81, No. 56, Page 15580]* on March 23, 2016, allowing for a 60-day public comment period. No comments were received for this information collection.

DATES: Comments are encouraged and will be accepted until August 1, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

5 CFR 837.103, Reemployment of Annuitants, requires agencies to collect information from retirees who become employed in Government positions. Agencies need to collect timely information regarding the type and amount of annuity being received so the correct rate of pay can be determined. Agencies provide this information to OPM so a determination can be made whether the reemployed retiree's annuity must be terminated.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management

Title: 5 CFR 837.103, Reemployment of Annuitants

OMB Number: 3206–0211

Frequency: On occasion

Affected Public: Individuals or Households

Number of Respondents: 3,000

Estimated Time per Respondent: 5 minutes

Total Burden Hours: 250

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–15497 Filed 6–29–16; 8:45 am]

BILLING CODE 6325–38–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 24, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 20 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–158, CP2016–229.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15463 Filed 6–29–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 24, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 228 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–157, CP2016–228.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15462 Filed 6–29–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service™.

ACTION: Notice of modification to existing systems of records.

SUMMARY: The United States Postal Service® (Postal Service) is proposing to modify two Customer Privacy Act Systems of Records (SOR). These changes are being made to support the automatic and seamless update of National Change of Address (NCOA) information, voluntarily provided by customers, in related customer databases that require the same NCOA information.

DATES: These revisions will become effective without further notice on August 1, 2016 unless comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be mailed or delivered to the Privacy and Records Office, United States Postal Service, 475 L'Enfant Plaza SW., Room 1P830, Washington, DC 20260–0004. Copies of all written comments will be available at this address for public inspection and photocopying between 8 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Janine Castorina, Chief Privacy Officer/A, Privacy and Records Office, 202–268–3089 or *privacy@usps.gov.*

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition, or when the agency establishes a new system of records. The Postal Service™ has determined that two Customer Privacy Act Systems of Records should be revised to modify the purpose(s).

I. Background

The Postal Service currently collects and stores information provided voluntarily by customers for the purpose of updating their address when they move from one location to another. Customers update their address through change-of-address, mail forwarding, or other related services. The USPS has determined that the provided information is needed to automatically update other related customer databases, including Customer Registration, that are presently separated from the NCOA database. The customer's new address information is needed in these separate databases so that requested products and services will continue to be received at their new address. These customer-based systems need to be integrated to meet customer needs and expectations, and to provide a positive customer experience. Current technological capabilities will be used to provide current and consistent capabilities across the systems to maintain the public's trust and to safeguard individual privacy.

II. Rationale for Changes to USPS Privacy Act Systems of Records

Privacy Act System of Records 800.000, Address Change, Mail Forwarding, and Related Services and 810.100, *www.usps.com* Registration are being modified to permit the Postal Service to use change-of-address data to support the update of customer profile information in Customer Registration, and other customer related systems. These modifications are needed to facilitate the accurate and reliable delivery and fulfillment of requested postal products, services, and materials to the customer's new address. Also, in an effort to increase the number of completed change-of-address requests, the Postal Service is proposing to add an additional purpose to SOR 800.000, which would allow communication between USPS customers and the Postal Service for the purpose of sending a reminder to customers who have started the change-of-address process online, but abandon the process before completion.

Also, due to organizational changes, the Postal Service is adding a System Manager and Address to SOR 800.000.

III. Description of Changes to Systems of Records

Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed modifications has been sent to Congress and to the Office of Management and Budget for their evaluations. The Postal Service does not expect these amended systems of records to have any adverse effect on individual privacy rights. The affected systems are as follows:

USPS 800.000

SYSTEM NAME:

Address Change, Mail Forwarding, and Related Services

* * * * *

PURPOSES:

[CHANGE TO READ]

* * * * *

6. To provide automatic updates to USPS customer systems using mail forwarding and change-of-address services.

7. To facilitate communication between USPS customers and the Postal Service with regard to change-of-address and address correction services.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

* * * * *

Vice President, Retail and Customer Service Operations, United States Postal Service, 475 L'Enfant Plaza SW., Washington, DC 20260.

* * * * *

USPS 810.100

SYSTEM NAME:

www.usps.com Registration

* * * * *

PURPOSES:

[CHANGE TO READ]

* * * * *

3. To maintain current and up-to-date address information to assure accurate and reliable delivery and fulfillment of postal products, services, and other material.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15461 Filed 6–29–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–32161]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

June 24, 2016.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of June 2016. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on July 19, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Hae-Sung Lee, Attorney-Adviser, at (202) 551–7345 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549–8010.

Oppenheimer SteelPath Master MLP Fund, LLC [File No. 811–22783]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On December 1, 2015, applicant made a liquidating distribution to its shareholders, based on net asset value. Applicant incurred no expenses in connection with the liquidation.

Filing Date: The application was filed on June 1, 2016.

Applicant's Address: 6803 S. Tucson Way, Centennial, CO 80112.

Private Advisors Alternative Strategies Master Fund [File No. 811–22646]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant is owned by one beneficial owner and does not propose to make a public offering of its securities. Applicant will continue to operate as a private investment fund in reliance on section 3(c)(1) or 3(c)(7) of the Act.

Filing Date: The application was filed on June 3, 2016.

Applicant's Address: 51 Madison Avenue, New York, NY 10010.

Private Advisors Alternative Strategies Fund [File No. 811–22647]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant is owned by one beneficial owner and does not propose to make a public offering of its securities. Applicant will continue to operate as a private investment fund in reliance on section 3(c)(1) or 3(c)(7) of the Act.

Filing Date: The application was filed on June 3, 2016.

Applicant's Address: 51 Madison Avenue, New York, NY 10010.

Tax-Exempt California Money Market Fund [File No. 811–05076]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On April 8, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $2,475 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on June 3, 2016.

Applicant's Address: 345 Park Avenue, New York, NY 10154.

Valley Forge Fund, Inc. [File No. 811–01932]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On May 31, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $16,582 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on June 13, 2016.

Applicant's Address: 3741 Worthington Road, Collegeville, PA 19426.

Charter National Variable Account [File No. 811–04588]

Summary: Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. The board of directors of the applicant's depositor, Charter National Life Insurance Company, approved the merger of applicant into Allstate Life Variable Life Separate Account A, which was effected on January 1, 2016. Expenses of $11,100 incurred in connection with the merger were paid by Allstate Life Insurance Company.

Filing Dates: The application was filed on April 22, 2016, and amended on June 16, 2016.

Applicant's Address: 3075 Sanders Road, Northbrook, IL 60062.

Oppenheimer Growth & Income Fund [File No. 811–07275]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on June 17, 2016.

Applicant's Address: 6803 S. Tucson Way, Centennial, CO 80112.

Transamerica Income Shares, Inc. [File No. 811–02273]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has transferred its assets to Transamerica Flexible Income, a series of Transamerica Funds and, on December 4, 2015, made a final distribution to its shareholders based on net asset value. Expenses of $80,310 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on June 9, 2016, and amended on June 20, 2016.

Applicant's Address: 1801 California Street, Suite 5200, Denver, CO 80202.

Direct Lending Income Fund [File No. 811–23123]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on June 3, 2016, and amended on June 20, 2016.

Applicant's Address: 1150 Foothill Boulevard, Suite F, La Canada, CA 91011.

BofA Funds Series Trust [File No. 811–22357]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has transferred its assets to corresponding series of BlackRock Liquidity Funds and, on April 18, 2016, made a final distribution to its shareholders based on net asset value. Expenses of approximately $1,834,000 incurred in connection with the reorganization were paid by the investment advisers of the applicant and the acquiring fund or their affiliates.

Filing Dates: The application was filed on June 1, 2016, and amended on June 22, 2016.

Applicant's Address: 100 Federal Street, Boston, MA 02110.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2016–15458 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78153; File No. SR–NYSE–2016–22]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 5 and 6, To Adopt Initial and Continued Listing Standards for the Listing of Equity Investment Tracking Stocks and Adopt Listing Fees Specific to Equity Investment Tracking Stocks

June 24, 2016.

I. Introduction

On April 7, 2016, the New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt initial and continued listing standards for the listing of Equity Investment Tracking Stocks and to adopt fees for Equity Investment Tracking Stocks. The proposed rule change was published for comment in the **Federal Register** on April 27, 2016.[3] On April 20, 2016, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded the original filing in its entirety.[4] On May 17, 2016, the Exchange filed Amendment No. 5 to the proposal, which superseded the filing, as amended by Amendment No. 1. Amendment No. 5 was published for comment in the **Federal Register** on

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77674 (April 21, 2016), 81 FR 24919 (April 27, 2016) ("Notice").

[4] On May 13, 2016, the Exchange submitted and withdrew Amendment No. 2 to the proposed rule change. On May 13, 2016, the Exchange filed Amendment No. 3 to the proposed rule change, and on May 16, 2016 the Exchange withdrew Amendment No. 3 to the proposed rule change. On May 16, 2016 the Exchange submitted Amendment No. 4 to the proposal, and on May 17, 2016, the Exchange withdrew Amendment No. 4 to the proposed rule change.

May 23, 2016.[5] On June 6, 2016, pursuant to Section 19(b)(2) of the Act,[6] the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[7] On June 23, 2016, the Exchange filed Amendment No. 6 to the proposed rule change.[8] The Commission received no comments on the proposed rule change, in response to either the original publication of the proposal in the **Federal Register**[9] or to the subsequent publication of the proposal as modified by Amendment No. 5.[10] This order grants approval of the proposed rule change, as modified by Amendment Nos. 5 and 6.

II. Description of the Proposed Rule Change

A. Listing Standards

The Exchange proposed to adopt initial and continued listing standards for the listing of Equity Investment Tracking Stocks. Proposed new Section 102.07 of the NYSE Listed Company Manual ("Manual") defines an Equity Investment Tracking Stock as a class of common equity securities that tracks on an unleveraged basis the performance of an investment by the issuer in the common equity securities of a single other company listed on the Exchange. An Equity Investment Tracking Stock may track multiple classes of common equity securities of a single issuer, so long as all of those classes have identical economic rights and at least one of those classes is listed on the Exchange.[11]

In order to qualify for initial listing under proposed Section 102.07, an Equity Investment Tracking Stock will be required to meet the distribution and public float requirements currently applicable to companies listing in connection with an initial public offering set forth in Sections 102.01A and 102.01B of the Manual, respectively, and the Global Market Capitalization Test set forth in Section 102.01C. Thus, at the time of initial listing an Equity Investment Tracking Stock will be required to: (i) Have at least 400 holders of 100 shares or more and 1,100,000 publicly held shares available for trading, as required under Section 102.01A; and (ii) have an aggregate market value of publicly-held shares of $40,000,000 and a price per share of $4 at the time of initial listing, as required under Section 102.01B.[12] In addition, at the time of initial listing the issuer of an Equity Investment Tracking Stock will be required to have $200 million in global market capitalization, as required under the Global Market Capitalization Test in Section 102.01C.[13]

Pursuant to proposed Section 102.07, the Exchange will not list an Equity Investment Tracking Stock if, at the time of the proposed listing, the issuer of the equity tracked by the Equity Investment Tracking Stock has been deemed below compliance with the Exchange's listing standards. In addition, the issuer of the Equity Investment Tracking Stock must own (directly or indirectly) at least 50% of both the economic interest and voting power of all of the outstanding classes of common equity securities of the issuer whose equity is tracked by the Equity Investment Tracking Stock.[14]

Proposed Section 102.07 provides that prior to the commencement of trading of any Equity Investment Tracking Stock, the Exchange will distribute an Information Memorandum to its Members and Member Organizations that includes (i) any special characteristics and risks of trading the Equity Investment Tracking Stock, and (ii) the Exchange Rules that will apply to the Equity Investment Tracking Stock including Exchange Rules that require Member Organizations: (a) To use reasonable diligence in regard to the opening and maintenance of every account, to know (and retain) the essential facts concerning every customer and concerning the authority of each person acting on behalf of such customer; and (b) in recommending transactions in the Equity Investment Tracking Stock to have a reasonable basis to believe that (1) the recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such Member Organization, and (2) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in the Equity Investment Tracking Stock.[15]

The Exchange proposed to subject Equity Investment Tracking Stocks to the same continued listing standards under Sections 802.01A and 802.01B of the Manual as are applicable to other common stock listed on the Exchange. Thus, an Equity Investment Tracking Stock will be considered to be below compliance with Section 802.01A if: (i) The number of total stockholders is less than 400; or (ii) the number of total stockholders is less than 1,200 and the average monthly trading volume is less than 100,000 shares (for the most recent 12 months); or (iii) the number of publicly-held shares is less than 600,000.[16] The issuer of an Equity Investment Tracking Stock will be deemed to be below compliance with Section 802.01B if its average global market capitalization over a consecutive 30 trading-day period is less than $50,000,000 and stockholders' equity is less than $50,000,000, and will be subject to immediate suspension and delisting procedures if its average global market capitalization over a consecutive 30 trading-day period is less than $15,000,000.[17]

In addition, the Exchange has proposed to review the continued listing status of an Equity Investment Tracking Stock if: (i) The listed equity security or securities whose value is tracked by the Equity Investment Tracking Stock ceases or cease to be listed on the Exchange; (ii) the issuer of the Equity Investment Tracking Stock owns

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[5] *See* Securities Exchange Act Release No. 77850 (May 17, 2016), 81 FR 32360 (May 23, 2016) ("Notice of Amendment No. 5").

[6] 15 U.S.C. 78s(b)(2).

[7] *See* Securities Exchange Act Release No. 77996 (June 6, 2016), 81 FR 37659 (June 10, 2016). The Commission designated July 26, 2016 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[8] In Amendment No. 6, the Exchange clarified the proposed rule change by deleting a representation that its existing surveillance procedures are generally adequate to properly monitor the trading of Equity Investment Tracking Stocks. The Commission notes that, as discussed further below, the Exchange will adopt enhanced surveillance procedures to enable it to monitor Equity Investment Tracking Stocks alongside the securities whose value they track. Additionally, the Exchange addressed a provision in proposed Section 102.07 that provides that the Exchange will not list an Equity Investment Tracking Stock if, at the time of the proposed listing, the issuer of the equity tracked by the Equity Investment Tracking Stock has been deemed below compliance with the Exchange's listing standards. The Exchange clarified that, for purposes of this provision, a company will be deemed to be below compliance if it has been identified as being below compliance for purposes of Sections 802.02 or 802.03 of the Listed Company Manual and subject to the procedures set forth in those rules. Amendment No. 6 is available at the Exchange's Web site and at *http://www.sec.gov/rules/sro/nyse.shtml*. Because Amendment No. 6 is a technical amendment that does not alter the substance of the proposed rule change, it is not subject to notice and comment.

[9] *See* Notice, *supra* note 3.

[10] *See* Notice of Amendment No. 5, *supra* note 5.

[11] *See* proposed Section 102.07 of the Manual.

[12] *See* Sections 102.01A and 102.01B of the Manual.

[13] *See* Section 102.01C of the Manual. In addition, an issuer of an Equity Investment Tracking Stock must fully comply with the Exchange's corporate governance requirements set forth in Section 303A of the Manual, subject to applicable exemptions such as those applicable to controlled companies. *See* Notice of Amendment No. 5, *supra* note 5, at 32361.

[14] *See* proposed Section 102.07 of the Manual.

[15] *See infra* note 38.

[16] *See* Section 802.01A of the Manual.

[17] *See* Section 802.01B of the Manual.

(directly or indirectly) less than 50% of either the economic interest or the voting power of all of the outstanding classes of common equity of the issuer whose equity is tracked by the Equity Investment Tracking Stock; or (iii) the Equity Investment Tracking Stock ceases to track the performance of the listed equity security or securities that was tracked at the time of initial listing.[18] In the event that any of the foregoing conditions exists, the Exchange will determine whether the Equity Investment Tracking Stock meets any other applicable initial listing standard in place at that time.[19] If the Equity Investment Tracking Stock does not qualify for initial listing at that time under another applicable listing standard, the issuer will not be eligible to follow the procedures set forth in Sections 802.02 and 802.03 of the Manual [20] and the Exchange will immediately suspend the Equity Investment Tracking Stock and commence delisting proceedings.[21] Furthermore, proposed Section 802.01B of the Manual provides that whenever trading in the equity security whose value is tracked by an Equity Investment Tracking Stock is suspended or delisting proceedings are commenced with respect to such security, such Equity Investment Tracking Stock will be suspended and/or delisting proceedings will be commenced with respect to such Equity Investment Tracking Stock at the same time.

The Exchange proposed to amend Section 202.06(B) of the Manual to provide that, in the event that the issuer of a common equity security tracked by an Equity Investment Tracking Stock intends to issue a material news release during the trading day and the Exchange determines to halt trading of such security under Section 202.06 pending dissemination of the news, or the Exchange implements any other required regulatory trading halt in a common equity security tracked by an Equity Investment Tracking Stock, the Exchange will also halt trading in the Equity Investment Tracking Stock that tracks the performance of such security. In such a case, the Exchange will halt trading of the Equity Investment Tracking Stock simultaneously with the halt in the common equity security being tracked and will also recommence trading in the two securities at the same time.[22]

The Exchange has represented that it will monitor activity in Equity Investment Tracking Stocks to identify and deter any potential improper trading activity in such securities and will adopt enhanced surveillance procedures to enable it to monitor Equity Investment Tracking Stocks alongside the common equity securities whose value is tracked by such stocks.[23] Additionally, the Exchange stated that it will rely on its existing trading surveillances, administered by the Exchange, or the Financial Industry Regulatory Authority ("FINRA") on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[24]

The Exchange has represented that it will conduct a review of compliance with continued listing standards of Equity Investment Tracking Stocks and their issuers and the trading characteristics of Equity Investment Tracking Stocks over the initial two year period that the proposed listing standard is in operation.[25] The Exchange has undertaken to provide the Commission with two reports based on this review, the first to be provided one year after the initial listing date of the first listed Equity Investment Tracking Stock and the second to be provided on the second anniversary of such initial listing date.[26] The Exchange has represented that, at a minimum, the reports will address the relationship between the trading prices of listed Equity Investment Tracking Stocks and those of the equity securities whose values they track, the liquidity of the market for the two securities, and any manipulation concerns arising in connection with the trading of Equity Investment Tracking Stocks and the securities whose values are being tracked.[27] The Exchange has represented that the reports will discuss any recommendations the Exchange may have for enhancements to the proposed listing standard based on its review.[28]

B. Proposed Fees

The Exchange proposed to amend Sections 902.02 and 902.03 of the Manual to adopt fees relating to Equity Investment Tracking Stocks. Specifically, the Exchange proposed to establish a fixed initial listing fee of $100,000 (inclusive of the one-time special charge of $50,000) [29] the first time an issuer lists an Equity Investment Tracking Stock that is the issuer's only class of common equity securities listed on the Exchange.[30] The Exchange proposed to charge the same annual fee for Equity Investment Tracking Stocks as it charges for an issuer's primary class of common shares, which is currently $0.001025 per share, subject to the minimum annual fee of $52,500.[31] The Exchange proposed to cap the total fees that may be billed in a calendar year ("Total Maximum Fee") to an issuer of an Equity Investment Tracking Stock at $200,000, so long as the Equity Investment Tracking Stock is the only class of common equity securities listed by the issuer on the Exchange.[32]

The Exchange further proposed to amend Section 907.00 of the Manual, which sets forth certain complimentary products and services that are offered to certain currently and newly listed issuers. Specifically, proposed Section 907.00 provides that the issuer of an Equity Investment Tracking Stock that is that issuer's only class of common equity securities listed on the Exchange will not receive the products and services provided for under Section 907.00, with the exception that such issuers will receive the complimentary products and services and access to discounted third-party products and services through the NYSE Market Access Center available to all listed issuers, as described on the Exchange's Web site. The Exchange stated that issuers of Equity Investment Tracking

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[18] *See* proposed Section 802.01B of the Manual. For avoidance of doubt, the Commission notes that the third prong does not refer to the situation in which the Equity Investment Tracking Stock price diverges from the price of the equity security that it tracks, but rather refers to the situation in which the Equity Investment Tracking Stock no longer seeks to track the performance of the listed equity security or securities that was tracked at initial listing and instead seeks to track one or more other assets.

[19] *Id.*

[20] Sections 802.02 and 803.03 of the Manual provide companies that have been identified as being below the Exchange's continued listing criteria with the opportunity to provide the Exchange with a plan of action the company has taken, or is taking, that will bring it into conformity with continued listing standards within 18 months.

[21] *See* proposed Section 802.01B of the Manual.

[22] *See* Notice of Amendment No. 5, *supra* note 5, at 32361–62.

[23] *Id.* at 32362.

[24] *See* Amendment No. 6, *supra* note 8. The Exchange stated that FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement; however, the Exchange is responsible for FINRA's performance under this regulatory services agreement. *Id.*

[25] *See* Notice of Amendment No. 5, *supra* note 5, at 32362.

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] The first time that an issuer lists a class of common shares, the issuer is subject to a one-time special charge of $50,000. *See* Section 902.03.

[30] *See* proposed Section 902.03. In contrast, initial listing fees the first time an issuer lists a class of common shares are charged at a rate of $0.0032 per share, subject to a minimum fee of $125,000 and a maximum fee of $250,000 (inclusive of the one-time special charge of $50,000). *See* Section 902.03.

[31] *See* proposed Section 902.03.

[32] *See* proposed Section 902.02. In contrast, the Total Maximum Fee for other listed companies is $500,000. *See* Section 902.02.

Stocks will be eligible for tier-based complimentary products and services set forth in Section 907.00 commencing when they have an additional class of common equity securities listed on the Exchange.[33] Proposed Section 907.00 further provides that in determining eligibility for the various service tiers under Section 907.00, the Exchange will aggregate all of the outstanding shares of listed classes of common equity securities of a company, including all outstanding shares of any listed Equity Investment Tracking Stock that is not the issuer's only listed class of common equity securities.[34]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[35] In particular, the Commission finds that the proposed rule change, as modified by Amendment Nos. 5 and 6, is consistent with Section 6(b)(5) of the Act,[36] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The development, implementation, and enforcement of standards governing the initial and continued listing of securities on an exchange are activities of critical importance to financial markets and the investing public. Listing standards, among other things, serve as a means for an exchange to screen issuers and to provide listed status only to bona fide companies that have or, in the case of an initial public offering, will have sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets. Once a security has been approved for initial listing, maintenance criteria allow an exchange to monitor the status and trading characteristics of that issue to ensure that fair and orderly markets can be maintained.

The Commission believes that the proposed quantitative and qualitative initial and continued listing standards for Equity Investment Tracking Stocks are consistent with the Act. These standards, which require issuers of Equity Investment Tracking Stocks to meet the quantitative and qualitative listing standards applicable to other common stock listed on the Exchange, should ensure that only substantial companies that are capable of meeting their financial obligations and have adopted robust corporate governance procedures can issue Equity Investment Tracking Stocks.[37]

The listing and trading of Equity Investment Tracking Stocks on the Exchange present unique issues by virtue of the fact that they are designed to track the performance of another publicly traded company. As a result, investors may expect that the trading price of an Equity Investment Tracking Stock will be related to the trading price of the tracked company and, as such, affected by news and information disclosed by such company. To address these issues, the Exchange has proposed to adopt additional requirements for the initial and continued listing of Equity Investment Tracking Stocks that are not applicable to other common stock listed on the Exchange.

These proposed listing standards require, among other things, that for the initial and continued listing of an Equity Investment Tracking Stock, the issuer of the equity security tracked by the Equity Investment Tracking Stock (the "tracked stock") must be listed on the Exchange and in good standing. Similarly, the proposed rules provide that whenever trading in the tracked stock is subject to a regulatory halt, or the tracked stock is suspended or delisting proceedings are commenced, trading in the Equity Investment Tracking Stock will also be halted, or the Equity Investment Tracking Stock will be suspended or delisting proceedings will be commenced, respectively.

The Commission believes that these additional requirements should protect investors and the public interest by assuring that pricing and other information with respect to the tracked stock is publicly available whenever the Equity Investment Tracking Stock is being traded. In addition, these requirements should help assure that the tracked stock is subject to comparable quantitative and qualitative requirements as the Equity Investment Tracking Stock, and that the Exchange has a listing relationship with, and direct access to information from, the issuer of the tracked stock.

In addition, the proposal requires that for initial and continued listing on the Exchange an issuer of an Equity Investment Tracking Stock must own, directly or indirectly, at least 50% of the economic interest and voting power of all of the outstanding classes of common equity securities of the issuer of the tracked stock. By effectively allowing only a single Equity Investment Tracking Stock to be issued for any tracked stock, and by requiring the issuer to be the controlling shareholder of the tracked stock, the Commission believes the proposal is reasonably designed to address concerns that the proliferation of tracking stocks could lead to undue market complexity or investor confusion.

Further, the Exchange has proposed to distribute an Information Memorandum prior to the commencement of trading apprising member firms of the special characteristics and risks of the Equity Investment Tracking Stock, as well as the Exchange's know-your-customer, suitability, and other rules applicable thereto.[38] The Commission believes distribution of this Information Memorandum should help address concerns, among others, that the complexity of an Equity Investment Tracking Stock and its relationship with the tracked stock could lead to investor confusion and create certain risks.

The Exchange also has represented that it will monitor activity in Equity Investment Tracking Stocks to identify and deter any potential improper trading activity in such securities and will adopt enhanced surveillance procedures to enable it to monitor Equity Investment Tracking Stocks together with the related tracked stocks. In addition, the Exchange has agreed to conduct a review both of compliance with continued listing standards and the trading characteristics of Equity Investment Tracking Stocks, provide certain reports to the Commission, and make any appropriate recommendations for enhancements to its listing standards for Equity Investment Tracking Stocks based on this review. The Commission believes these measures should reduce the risks of manipulative or other improper activity in connection with Equity Investment Tracking Stocks, help assure compliance with the proposed listing standards, and identify areas where such standards might need to be strengthened going forward.

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[33] *See* Notice of Amendment No. 5, *supra* note 5, at 32363.

[34] The Exchange's proposal also makes minor changes to the rule text to: (i) Remove obsolete language from Sections 802.01B and 902.03, and (ii) update a Web site link included in Section 907.00.

[35] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[36] 15 U.S.C. 78f(b)(5).

[37] *See supra* notes 12–13.

[38] *See, e.g.,* NYSE Rules 2090 and 2111 (requiring member organizations to, among other things, use due diligence to learn the essential facts relative to every customer prior to trading or recommending a transaction in an Equity Investment Tracking Stock and have a reasonable basis to believe that a customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in an Equity Investment Tracking Stock).

With respect to the proposed fees, the Commission believes it is consistent with the Act for the Exchange to exclude issuers whose only common equity security listed on the Exchange is an Equity Investment Tracking Stock from receiving the complimentary products and services provided for under Section 907.00 of the Manual. The Exchange stated that most of the services provided under Section 907.00 would be of limited value and appeal to issuers of Equity Investment Tracking Stocks.

Finally, the Commission believes that the proposed listing and annual fees for Equity Investment Tracking Stocks are an equitable allocation of reasonable fees. The Exchange stated that it is appropriate to charge lower fees to issuers whose only common equity security listed on the Exchange is an Equity Investment Tracking Stock because there are regulatory efficiencies for the Exchange when the issuer of an Equity Investment Tracking Stock and the issuer of the tracked stock are both listed on the Exchange. The Exchange represented that it does not believe that the proposed fees would negatively affect its ability to continue to adequately fund its regulatory program or the services the Exchange provides to issuers. According to the Exchange, these lower fees also reflect the fact that issuers whose only listed security is an Equity Investment Tracking Stock will not receive the complimentary products and services that other listed issuers of equity securities are eligible for under Section 907.00 of the Manual.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[39] that the proposed rule change (SR–NYSE–2016–22), as modified by Amendment Nos. 5 and 6, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

Brent J. Fields,

Secretary.

[FR Doc. 2016–15457 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

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[39] 15 U.S.C. 78s(b)(2).

[40] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78154; File No. SR–NYSE–2016–46]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change for a Temporary Suspension of Those Aspects of Rules 36.20 and 36.21 That Would Not Permit Floor Brokers To Use Personal Portable Phone Devices on the Trading Floor Due to the Unavailability of Floor Broker Telephone Services

June 24, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 24, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a temporary suspension of those aspects of Rules 36.20 and 36.21 that would not permit Floor brokers to use personal portable phone devices on the Trading Floor due to the unavailability of Floor broker telephone services on June 24, 2016. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to temporarily suspend those aspects of Rules 36.20 and 36.21 that would not permit Floor brokers to use personal portable phone devices on the Trading Floor.[4] As proposed, all other aspects of Rule 36 remain applicable and the temporary suspensions of the applicable Rule 36 requirements are in effect on June 24, 2016 only.[5]

On June 24, 2016, the third-party carrier that provides service for the wired phone lines for Floor brokers experienced an issue that affected the availability of those phone lines. This suspension of service only impacted the service for telephone service for Floor brokers and did not impact phone service for Designated Market Makers. The Exchange is working closely with the third-party carrier to restore such phone service.

Rules 36.20 and 36.21 govern the type of telephone communications that are approved for Floor brokers. Pursuant to Rule 36.20, Floor brokers may maintain a telephone line on the Trading Floor and use Exchange authorized and provided portable phones while on the Trading Floor. The use of such Exchange authorized and provided portable phones is governed by Rule 36.21. Because of the issues with the third-party carrier, Floor brokers are unable to reach their customers via their third-party carrier wired telephone lines. While Exchange-provided portable phones are operating, not all Floor brokers have Exchange-provided and authorized portable phones. However, the personal cell phones of Floor brokers are operational on the Trading Floor. The Exchange believes that because communications with customers is a vital part of a Floor broker's role as agent and therefore contributes to maintaining a fair and orderly market, during the period when the phone lines are non-operational, Floor brokers who do not have Exchange authorized and provided portable phones should be permitted to use personal cell phone devices in lieu of the non-operational wired phone lines.[6]

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Pursuant to Rule 6A, the Trading Floor is defined as the restricted-access physical areas designated by the Exchange for the trading of securities.

[5] The Exchange provided Floor brokers with notice of this rule filing, including the applicable recordkeeping and other requirements related to using personal cell phones during the temporary suspension of Rule 36.

The Exchange therefore proposes to temporarily suspend the limitations in Rules 36.20 and 36.21 that permit Floor brokers to use only Exchange authorized and provided portable phones so that Floor brokers who do not have an Exchange authorized and portable phone may use personal cell phones on the Trading Floor. The Exchange proposes that pursuant to this temporary suspension, Floor brokers must provide the Exchange with the names of all Floor-based personnel who used personal portable phones during this temporary suspension period, together with the phone number and applicable carrier for each number. Floor broker member organizations must maintain in their books and records all cell phone records that show both incoming and outgoing calls that were made during the period that a personal portable phone was used on the Trading Floor. To the extent the records are unavailable from the third-party carrier, the Floor brokers must maintain contemporaneous records of all calls made or received on a personal portable phone while on the Trading Floor. As with all member organization records, such cell phone records must be provided to Exchange regulatory staff on request.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

In particular, because of issues experienced by a third-party phone carrier, wired phone lines are not functional. The Exchange believes that the proposed temporary suspensions from those aspects of Rule 36 that restrict Floor broker's use of personal portable phones on the Trading Floor removes impediments to and perfects the mechanism of a free and open market and national market system because the proposed relief will enable Floor brokers who do not have an Exchange authorized and provided portable phone to conduct their regular business, notwithstanding the ongoing issues with telephone service. The Exchange further believes that without the requested relief, Floor brokers would be compromised in their ability to conduct their regular course of business on the Trading Floor. In particular, for Floor brokers, because they operate as agents for customers, their inability to communicate with customers could compromise their ability to represent public orders on the Trading Floor.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on competition because the proposed change only impacts Floor brokers and has no change in operations for other market participants or other market centers. To the contrary, the Exchange believes that without the proposed relief, Floor brokers would be compromised in their ability to conduct their regular course of business on the Trading Floor, thereby placing a burden on the Floor brokers' ability to compete.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) under the Act[12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. In support of the request, the Exchange states that waiver the 30-day operative delay will allow the Exchange to invoke the relief immediately upon filing, which is necessary so that Floor brokers may be able to communicate with their customers on a day with significantly increased volumes of trading due both to the United Kingdom referendum vote to leave the European Union and the rebalancing of the Russell Investment Group indices after the close of trading on June 24, 2016. Based on the above, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because it will permit Floor brokers to remain in communication with customers while wired phone lines are unavailable. Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

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[6] To the extent that the wired phone lines are operational, Floor brokers must use those phone lines rather than use a personal cell phone.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has determined to waive the five-day prefiling period in this case.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78s(b)(2)(B).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2016–46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–46. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–46 and should be submitted on or before July 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–15499 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

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[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78150; File No. SR–NASDAQ–2016–086]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change to List and Trade the Shares of the VanEck Vectors Long/Flat Commodity ETF

June 24, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 10, 2016, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade the shares of the VanEck Vectors Long/Flat Commodity ETF (the "Fund"), a series of VanEck Vectors ETF Trust ("Trust"), under Nasdaq Rule 5735 ("Managed Fund Shares"). The shares of the Fund are collectively referred to herein as the "Shares."

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/*, at Nasdaq's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares of the Fund under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares[3] on the Exchange.[4] The Fund will be an actively managed exchange-traded fund ("ETF"). The Shares will be offered by the Trust, which was organized as a Delaware statutory trust on March 15, 2001.[5] The Trust is registered with the Commission as an investment company and has filed a registration statement on Form N–1A ("Registration Statement") with the Commission.[6] The Fund is a series of the Trust.

Van Eck Absolute Return Advisers Corporation will be the investment adviser ("Adviser") and the administrator to the Fund. Van Eck Securities Corporation ("Distributor") will be the distributor of the Fund's Shares. The Bank of New York Mellon ("Custodian") will act as the custodian of the Fund's assets and provide transfer agency and fund accounting services to the Fund.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (the "1940 Act") organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Index Fund Shares, listed and traded on the Exchange under Nasdaq Rule 5705, seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[4] The Commission approved Nasdaq Rule 5735 in Securities Exchange Act Release No. 57962 (June 13, 2008), 73 FR 35175 (June 20, 2008) (SR–NASDAQ–2008–039). The Fund would not be the first actively-managed fund listed on the Exchange; *see* Securities Exchange Act Release No. 66489 (February 29, 2012), 77 FR 13379 (March 6, 2012) (SR–NASDAQ–2012–004) (order approving listing and trading of WisdomTree Emerging Markets Corporate Bond Fund). The Exchange believes the proposed rule change raises no significant issues not previously addressed in those prior Commission orders.

[5] The Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act (the "Exemptive Order"). *See* Investment Company Act Release No. 29571 (January 24, 2011) (File No. 812–13601). In compliance with Nasdaq Rule 5735(b)(5), which applies to Managed Fund Shares based on an international or global portfolio, the Trust's application for exemptive relief under the 1940 Act states that the Fund will comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with redemption securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933 (15 U.S.C. 77a).

[6] *See* Registration Statement on Form N–1A for the Trust, dated November 12, 2015 (File Nos. 333–123257 and 811–10325). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement.

Paragraph (g) of Rule 5735 provides that if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a "fire wall" between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[7] In addition, paragraph (g) further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the open-end fund's portfolio. Rule 5735(g) is similar to Nasdaq Rule 5705(b)(5)(A)(i); however, paragraph (g) operates in connection with the establishment of a "fire wall" between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds.

The Adviser is not a broker-dealer, although it is affiliated with the Distributor, a broker-dealer. The Adviser has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the Fund's (including the Subsidiary's) portfolio.

In the event (a) the Adviser becomes newly affiliated with a broker-dealer or registers as a broker-dealer, or (b) any new adviser or sub-adviser to the Fund is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, if applicable, regarding access to information concerning the composition and/or changes to the portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio. The Fund does not currently intend to use a sub-adviser.

VanEck Vectors Long/Flat Commodity ETF

The Fund's investment objective will be to seek long-term capital appreciation while seeking to manage volatility and reduce downside risk during sustained market declines.

Principal Investment Strategies

The Fund will be an actively managed ETF that seeks to achieve its investment objective by investing, under normal circumstances, in exchange-traded commodity futures contracts and, under certain limited circumstances, other commodity-linked instruments ("Other Commodity Instruments"[8] and, collectively with exchange-traded commodity futures contracts, "Commodities Instruments").

The Fund will invest in Commodities Instruments primarily through a wholly-owned subsidiary of the Fund organized under the laws of the Cayman Islands ("Subsidiary"). The Subsidiary will be advised by the Adviser.

With respect to the exchange-traded commodity futures contracts and options on futures contracts (if applicable) held, not more than 10% of the weight[9] of such futures contracts and options on futures contracts in the aggregate shall consist of instruments whose principal trading market is not a member of the Intermarket Surveillance Group ("ISG") or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement.

The Fund (directly or indirectly through the Subsidiary) will normally invest in exchange-traded commodity futures contracts that are components of the Morningstar® Long/Flat Commodity Index℠ ("Benchmark"), an index composed of futures contracts on 20 heavily traded commodities across the energy, agriculture, industrial metals, precious metals, and livestock sectors. The Adviser will employ a rules-based investment approach when selecting Commodities Instruments based upon momentum characteristics of the Commodities Instruments. Commodities Instruments are assessed on a monthly basis by comparing current prices to 12-month moving averages. The Fund's positions will be either long[10] or flat.[11] The Fund intends to take long positions in those Commodities Instruments whose prices are above their 12-month moving average. Conversely, the Fund intends to take flat positions to manage volatility and reduce downside risk for those Commodities Instruments whose prices are below their 12-month moving average. The Fund will not be an "index tracking" ETF and may not always invest in all of the Benchmark's components, or in the same proportion, and it may invest in Commodities Instruments outside the Benchmark.

The Subsidiary will be an exempted company operating under Cayman Islands law. It will be wholly-owned and controlled by the Fund and will be advised by the Adviser. The Fund's investment in the Subsidiary may not exceed 25% of the value of the Fund's total assets at each quarter-end of the Fund's fiscal year. The Fund's investment in the Subsidiary is expected to provide the Fund with exposure to Commodities Instruments within the limits of the federal tax laws, which limit the ability of investment companies like the Fund to invest directly in such instruments. The Subsidiary will have the same investment objective as the Fund and will follow the same general investment policies and restrictions, except that unlike the Fund, it may invest without limit in Commodities Instruments.

The Fund (and the Subsidiary, as applicable) expects to invest its remaining assets in any one or more of the following: U.S. government securities,[12] money market funds, cash

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[7] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the "Advisers Act"). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[8] Other Commodity Instruments will include commodity-based swap agreements cleared through a central clearing house or the clearing house's affiliate ("Cleared Swaps"), forward contracts on commodities, exchange-traded options on futures contracts, and commodity-based swaps other than Cleared Swaps.

[9] To be calculated as the value of the contract divided by the total absolute notional value of the Fund's futures contracts and options on futures contracts.

[10] A "long" position is a position that will increase in market price if the price of the commodity futures contract is rising during the period when the position is open.

[11] A "flat" position is a position that will not increase or decrease in market price whether the price of the commodity futures contract to which it relates is rising or falling.

[12] Such securities will include securities that are issued or guaranteed by the U.S. Treasury, by various agencies of the U.S. government, or by

Continued

and other cash equivalents,[13] treasury inflation-protected securities, sovereign debt obligations of non-U.S. countries and repurchase agreements that provide liquidity, serve as margin or collateralize the Fund's or the Subsidiary's investments in exchange-traded commodity futures contracts.

The Fund also may invest directly in ETFs, exchange-traded closed end funds (to the extent permitted by the 1940 Act, and certain exemptive relief therefrom), and exchange-traded notes ("ETNs") that provide exposure to commodities.[14]

As previously noted, the Subsidiary will be advised by the Adviser.[15] The Subsidiary will typically consider investing in futures contracts of the Benchmark ("Index Commodity Contracts") set forth in the following table. The table also provides each instrument's trading hours, exchange ("Futures Exchange") and ticker symbol. The table is subject to change.

Contract ticker (Bloomberg generic)	Exchange code (Bloomberg)[16]	Exchange name[17]	Commodity contract	Trading hours (ET)
BO1	CBT	Chicago Board of Trade	Soybean Oil/Crude	20:00–14:20
C 1	CBT	Chicago Board of Trade	Corn/No. 2 Yellow	20:00–14:20
CO1	ICE	ICE Futures Europe Commodities	Crude Oil Brent/Global Spot	20:00–18:00
CL1	NYM	New York Mercantile Exchange	Crude Oil WTI/Global Spot	18:00–17:15
CT1	NYB	ICE Futures US Softs	Cotton/1 1⁄16″	21:00–14:20
GC1	CMX	Commodity Exchange, Inc	Gold	18:00–17:15
HG1	CMX	Commodity Exchange, Inc	Copper High Grade/Scrap No. 2 Wire	18:00–17:15
HO1	NYM	New York Mercantile Exchange	Heating Oil #2/Fuel Oil	18:00–17:15
KC1	NYB	ICE Futures US Softs	Coffee 'C'/Colombian	04:15–13:30
LC1	CME	Chicago Mercantile Exchange	Cattle Live/Choice Average	09:00–17:00
QS1	ICE	ICE Futures Europe Commodities	Gas-Oil-Petroleum	20:00–18:00
LH1	CME	Chicago Mercantile Exchange	Hogs Lean/Average Iowa/S Minn	09:00–17:00
NG1	NYM	New York Mercantile Exchange	Natural Gas Henry Hub	18:00–17:15
XB1	NYM	New York Mercantile Exchange	Gasoline Blendstock	18:00–17:15
S 1	CBT	Chicago Board of Trade	Soybeans/No. 2 Yellow	20:00–14:20
SB1	NYB	ICE Futures US Softs	Sugar #11/World Raw	03:30–13:00
SI1	CMX	Commodity Exchange, Inc	Silver	18:00–17:15
SM1	CBT	Chicago Board of Trade	Soybean Meal/48% Protein	20:00–14:20
W 1	CBT	Chicago Board of Trade	Wheat/No. 2 Soft Red	20:00–14:20
CC1	NYB	ICE Futures US Softs	Cocoa/Ivory Coast	04:45–13:30

As U.S. and London exchanges list additional contracts, as currently listed contracts on those exchanges gain sufficient liquidity or as other exchanges list sufficiently liquid contracts, the Adviser may include those contracts in the list of possible investments of the Subsidiary. The list of commodities futures and commodities markets considered for investment may change over time.

Other Investments

The Fund currently intends to invest first in exchange-traded commodity futures contracts. Thereafter, if the Fund reaches the position limits applicable to one or more Index Commodity Contracts or a Futures Exchange imposes limitations on the Fund's ability to maintain or increase its positions in an exchange-traded commodity futures contract after reaching accountability levels or a price limit is in effect on an exchange-traded commodity futures contract during the last 30 minutes of its regular trading session, the Fund's intention is to invest first in Cleared Swaps to the extent permitted under the position limits applicable to Cleared Swaps and appropriate in light of the liquidity in the Cleared Swaps market, and then, using its commercially reasonable judgment, in Other Commodity Instruments.

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various instrumentalities, which have been established or sponsored by the U.S. government. U.S. Treasury obligations are backed by the "full faith and credit" of the U.S. government. Securities issued or guaranteed by federal agencies and U.S. government-sponsored instrumentalities may or may not be backed by the full faith and credit of the U.S. government.

[13] Cash equivalents will include banker's acceptances, commercial paper, and certificates of deposit.

[14] An ETF is an investment company registered under the 1940 Act that holds a portfolio of securities. Many ETFs are designed to track the performance of a securities index, including industry, sector, country and region indexes. ETFs in which the Fund invests will be listed and traded in the U.S. on registered exchanges. The ETFs in which the Fund will invest include Index Fund Shares (as described in Nasdaq Rule 5705), Portfolio Depositary Receipts (as described in Nasdaq Rule 5705), and Managed Fund Shares (as described in Nasdaq Rule 5735). The shares of ETFs in which the Fund may invest will be limited to securities that trade in markets that are members of the ISG, which includes all U.S. national securities exchanges, or exchanges that are parties to a comprehensive surveillance sharing agreement with the Exchange. An ETN is a senior, unsecured, unsubordinated debt security issued by an underwriting bank that, similar to other debt securities, has a maturity date and is backed only by the credit of the issuer. ETNs in which the Fund invests will be listed and traded in the U.S. on registered exchanges. The ETNs in which the Fund will invest include Securities Linked to the Performance of Indexes and Commodities, Including Currencies (as described in Nasdaq Rule 5710), and Index-Linked Exchangeable Notes (as described in Nasdaq Rule 5711). The Fund will not hold inverse, leveraged, and inverse leveraged ETFs or ETNs. Leveraged instruments are operated in a manner designed to seek a multiple of the performance of an underlying reference index, and inverse instruments are designed to seek investment results that correspond to the inverse (opposite) of the performance of a specified domestic equity, international or global equity, or fixed income index or a combination thereof.

[15] The Subsidiary will not be registered under the 1940 Act and will not be directly subject to its investor protections, except as noted in the Registration Statement. However, the Subsidiary will be wholly-owned and controlled by the Fund and will be advised by the Adviser. The Trust's board ("Board") will have oversight responsibility for the investment activities of the Fund, including its investment in the Subsidiary, and the Fund's role as the sole shareholder of the Subsidiary. The Adviser will receive certain fees for managing the Subsidiary's assets and the Adviser will waive or credit such amounts against the fees payable to the Adviser by the Fund. It is expected that the Subsidiary will become party to the existing custody agreement, transfer agency agreement and accounting agreement of the Trust and Fund.

[16] The exchange codes listed are Bloomberg shorthand codes for the corresponding exchanges. The New York Board of Trade is currently owned by the ICE Futures Exchange; Bloomberg continues to use NYB as its shorthand code for certain contracts formerly traded on the New York Board of Trade.

[17] All of the exchanges are ISG members.

The Fund may also invest in commodity-related foreign and domestic equity securities.[18]

Commodities Regulation

The Commodity Futures Trading Commission ("CFTC") has recently adopted substantial amendments to CFTC Rule 4.5 relating to the permissible exemptions and conditions for reliance on exemptions from registration as a commodity pool operator.[19] As a result of the amendments and based on the Fund's and its Subsidiary's current investment strategies, the Fund and the Subsidiary will each be a "commodity pool" and the Adviser, which is currently registered with the CFTC as a commodity pool operator ("CPO") and a commodity trading adviser under the Commodity Exchange Act of 1936, is considered a CPO with respect to the Fund and the Subsidiary. The Adviser is also a member of the National Futures Association ("NFA"). The Fund will be and the Adviser is subject to regulation by the CFTC and the Commission and additional disclosure, reporting and recordkeeping rules imposed upon commodity pools.

Investment Restrictions of the Fund[20]

The Fund may not make loans, except that it may (i) lend portfolio securities, (ii) enter into repurchase agreements, (iii) purchase all or a portion of an issue of debt securities, bank loan or participation interests, bank certificates of deposit, bankers' acceptances, debentures or other securities, whether or not the purchase is made upon the original issuance of the securities, and (iv) participate in an interfund lending program with other registered investment companies, all in accordance with the 1940 Act.

The Fund may not borrow money, except as permitted under the 1940 Act, and as interpreted or modified by regulation from time to time. The Fund also may not issue senior securities, except as permitted under the 1940 Act, and as interpreted or modified by regulation from time to time.

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment).[21] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.[22] An illiquid security is generally considered to be a security that cannot be sold or disposed of in the ordinary course of business within seven days at or near its carrying value.

The Fund may not purchase any security if, as a result of that purchase, 25% or more of its total assets would be invested in securities of issuers having their principal business activities in the same industry. This limit does not apply to securities issued or guaranteed by the U.S. Government, its agencies or instrumentalities, or securities of other investment companies.

Determination of Net Asset Value

The net asset value ("NAV") per Share for the Fund will be computed by dividing the value of the net assets of the Fund (*i.e.,* the value of its total assets less total liabilities) by the total number of Shares outstanding. Expenses and fees, including the management fee, will be accrued daily and taken into account for purposes of determining NAV. The NAV of the Fund will be determined each business day as of the close of trading (ordinarily 4:00 p.m. Eastern Time) on the Nasdaq. Any assets or liabilities denominated in currencies other than the U.S. dollar will be converted into U.S. dollars at the current market rates on the date of valuation as quoted by one or more sources.

The values of the Fund's portfolio securities will be valued in accordance with the Trust's valuation policies and procedures which may be amended from time to time. Included herein is a description of how various types of securities and instruments will be valued based on the current valuation policies and procedures for the Trust. ETFs, exchange-traded closed-end funds, ETNs, and commodity-related foreign and domestic equity securities, will be based on the securities' closing prices on local markets, when available. Due to the time differences between the United States and certain countries, securities on these non-U.S. exchanges may not trade at times when Shares of the Fund will trade. In the absence of a last reported sales price, or if no sales were reported, and for other assets for which market quotes are not readily available, values may be based on quotes obtained from a quotation reporting system, established market makers or by an outside independent pricing service using data reflecting the earlier closing of the principal markets for those securities. U.S. government securities, treasury inflation-protected securities and sovereign debt obligations of non-U.S. countries will normally be valued on the basis of quotes from brokers or dealers, established market makers or an outside independent pricing service. Short-term investments purchased with a remaining maturity of 60 days or less, including repurchase agreements and cash equivalents, will be valued on the basis of quotes from broker dealers, established major market makers, an independent pricing service or at amortized cost. Money market funds will be valued at their reported closing NAV. Futures contracts and options on futures contracts, which are traded on exchanges, will be valued at the current settle price for like contracts acquired on the day on which the futures contract will be valued as of the close of such exchanges.

Other Commodity Instruments not traded on exchanges will generally be valued daily based upon quotations from market makers or by a pricing service and in accordance with the Trust's valuation policies and procedures. Prices obtained by an outside independent pricing service may use information provided by market makers or estimates of market values obtained from yield data related to investments or securities with similar characteristics and may use a computerized grid matrix of securities and its evaluations in determining what it believes is the fair value of the portfolio securities. If a market quotation for a security is not readily available or the Adviser believes it does not otherwise accurately reflect the market value of the security at the time the Fund calculates its NAV, the security will be fair valued by the Adviser in accordance with the Trust's valuation policies and procedures approved by the Board of Trustees.

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[18] Commodity-related foreign and domestic equity securities will be comprised of exchange-traded common stocks of companies that operate in commodities, natural resources and energy businesses, and in associated businesses, as well as companies that provide services or have exposure to such businesses.

[19] 17 CFR 4.5. *See, e.g.,* 77 FR 11252 (Feb. 24, 2014); 77 FR 17328 (March 26, 2012).

[20] Percentage limitations of the investment restrictions set forth herein are measured at the time of investment.

[21] In reaching liquidity decisions, the Adviser may consider factors such as but not limited to the following: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace in which it trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers and the mechanics of transfer).

[22] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding "Restricted Securities"); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

The Fund may also use fair value pricing in a variety of circumstances, including but not limited to, situations when the value of a security or instrument in the Fund's portfolio has been materially affected by events occurring after the close of the market on which the security or instrument is principally traded (such as a corporate action or other news that may materially affect the price of a security) or trading in a security or instrument has been suspended or halted.

In addition, the Fund expects that it will fair value certain of the foreign equity securities held by the Fund each day it calculates its NAV, except those securities principally traded on exchanges that close at the same time the Fund calculates its NAV. Accordingly, the Fund's NAV may reflect certain portfolio securities' or instruments' fair values rather than their market prices at the time the exchanges on which they principally trade close. Fair value pricing involves subjective judgments and it is possible that a fair value determination for a security or instrument will be materially different than the value that could be realized upon the sale of the security or instrument. With respect to securities or instruments that are principally traded on foreign exchanges, the value of the Fund's portfolio securities or instruments may change on days when you will not be able to purchase or sell your Shares.

Creation and Redemption of Shares

The Trust will issue and sell Shares of the Fund only to authorized participants ("Authorized Participants") and only in aggregations of 50,000 Shares (each, a "Creation Unit"), on a continuous basis through the Distributor, without an initial sales load, at their NAV next determined after receipt, on any Business Day,[23] of an order in proper form.

The consideration for a purchase of Creation Units will generally consist of cash and/or the in-kind deposit of a designated portfolio of securities ("Deposit Securities") and an amount of cash computed as described below ("Cash Component"). The Cash Component together with the Deposit Securities, as applicable, will be referred to as the "Fund Deposit," which represents the minimum initial and subsequent investment amount for Shares. The Cash Component will represent the difference between the NAV of a Creation Unit and the market value of Deposit Securities and may include a Dividend Equivalent Payment. The "Dividend Equivalent Payment" will enable the Fund to make a complete distribution of dividends on the next dividend payment date, and will be an amount equal, on a per Creation Unit basis, to the dividends on all the securities held by the Fund ("Fund Securities") with ex-dividend dates within the accumulation period for such distribution (the "Accumulation Period"), net of expenses and liabilities for such period, as if all of the Fund Securities had been held by the Trust for the entire Accumulation Period. The Accumulation Period will begin on the ex-dividend date for the Fund and will end on the next ex-dividend date.

The Administrator, through the NSCC, will make available on each Business Day, immediately prior to the opening of business on the Exchange (currently 9:30 a.m. Eastern Time), the list of the names and the required number of shares of each Deposit Security to be included in the current Fund Deposit (based on information at the end of the previous Business Day) as well as the Cash Component for the Fund. Such Fund Deposit will be applicable, subject to any adjustments as described below, in order to effect creations of Creation Units of the Fund until such time as the next-announced Fund Deposit composition is made available.

The identity and number of shares of the Deposit Securities required for the Fund Deposit for the Fund may change as rebalancing adjustments and corporate action events occur from time to time. In addition, the Trust will reserve the right to accept a basket of securities or cash that differs from Deposit Securities or to permit or require the substitution of an amount of cash (*i.e.*, a "cash in lieu" amount) to be added to the Cash Component to replace any Deposit Security which may, among other reasons, not be available in sufficient quantity for delivery or not be permitted to be re-registered in the name of the Trust as a result of an in-kind creation order pursuant to local law or market convention or which may not be eligible for transfer through the Clearing Process, or which may not be eligible for trading by a Participating Party (defined below).

In light of the foregoing, in order to seek to replicate the in-kind creation order process, the Trust expects to purchase the Deposit Securities represented by the cash in lieu amount in the secondary market ("Market Purchases"). In such cases where the Trust makes Market Purchases because a Deposit Security may not be permitted to be re-registered in the name of the Trust as a result of an in-kind creation order pursuant to local law or market convention, or for other reasons, the Authorized Participant will reimburse the Trust for, among other things, any difference between the market value at which the securities were purchased by the Trust and the cash in lieu amount (which amount, at the Adviser's discretion, may be capped), applicable registration fees and taxes.

Brokerage commissions incurred in connection with the Trust's acquisition of Deposit Securities will be at the expense of the Fund and will affect the value of all Shares of the Fund; but the Adviser may adjust the transaction fee to the extent the composition of the Deposit Securities changes or cash in lieu is added to the Cash Component to protect ongoing shareholders. The adjustments described above will reflect changes, known to the Adviser on the date of announcement to be in effect by the time of delivery of the Fund Deposit, resulting from stock splits and other corporate actions.

In addition to the list of names and numbers of securities constituting the current Deposit Securities of the Fund Deposit, the Administrator, through the NSCC, will also make available (i) on each Business Day, the Dividend Equivalent Payment, if any, and the estimated Cash Component effective through and including the previous Business Day, per outstanding Shares of the Fund, and (ii) on a continuous basis throughout the day, the Indicative Optimized Portfolio Value ("IOPV").

To be eligible to place orders with the Distributor to create and redeem

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[23] A "Business Day" with respect to the Fund is any day on which Nasdaq is open for business. As of the date of this filing, the Nasdaq observes the following holidays: New Year's Day, Martin Luther King, Jr. Day, President's Day (Washington's Birthday), Good Friday, Memorial Day (observed), Independence Day, Labor Day, Thanksgiving Day, and Christmas Day.

Creation Units of the Fund, an Authorized Participant must be (1) a "Participating Party," *i.e.*, a broker-dealer or other participant in the Clearing Process through the Continuous Net Settlement System of the NSCC; or (2) a DTC Participant; and, in either case, must have executed an agreement with the Distributor and the Transfer Agent (as it may be amended from time to time in accordance with its terms) with respect to the purchases and redemptions of Creation Units. All Creation Units of the Fund, however created, will be entered on the records of the Depository in the name of Cede & Co. for the account of a DTC Participant.

All orders to create Creation Units must be received by the Distributor no later than the closing time of the regular trading session on Nasdaq ("Closing Time") (ordinarily 4:00 p.m., Eastern Time) on the date such order is placed in order for creation of Creation Units to be effected based on the NAV of the Fund as determined on such date.

Shares may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Distributor, only on a Business Day and only through a Participating Party or DTC Participant who has executed a Participant Agreement. In order to redeem Creation Units, an Authorized Participant must submit an order to redeem for one or more Creation Units. All such orders must be received by the Distributor in proper form no later than Closing Time in order to receive the day's closing NAV per share.

To the extent the Fund's redemptions are effected in-kind, the Administrator, through NSCC, makes available immediately prior to the opening of business on the Exchange (currently, 9:30 a.m., Eastern Time) on each day that the Nasdaq is open for business, the Fund Securities that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form (as defined below) on that day.

Unless cash redemptions are permitted or required for the Fund, the redemption proceeds for a Creation Unit generally consist of Fund Securities as announced by the Administrator on the Business Day of the request for redemption, plus cash in an amount equal to the difference between the NAV of the Shares being redeemed, as next determined after a receipt of a request in proper form, and the value of the Fund Securities, less the redemption transaction fee and applicable variable fees. Should the Fund Securities have a value greater than the NAV of the Shares being redeemed, a compensating cash payment to the Trust equal to the differential plus the applicable redemption transaction fee will be required to be arranged for by or on behalf of the redeeming shareholder. The Fund reserves the right to honor a redemption request by delivering a basket of securities or cash that differs from the Fund Securities.

Availability of Information

The Fund's Web site (*www.vaneck.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Fund's Web site will include additional quantitative information updated on a daily basis, including, for the Fund: (1) The prior business day's reported NAV and closing price, and a calculation of the premium and discount of the closing price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio as defined in Nasdaq Rule 5735(c)(2) that will form the basis for the Fund's calculation of NAV at the end of the business day.[24]

On a daily basis, the Fund will disclose on the Fund's Web site the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding), the identity of the security or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and percentage weighting of the holding in the Fund's portfolio. The Web site information will be publicly available at no charge.

In addition, a basket composition file, which includes the security names and quantities required to be delivered in exchange for the Fund's Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the Exchange via NSCC. The basket represents one Creation Unit of the Fund.

Also, for the Fund, an IOPV,[25] defined in Rule 5735(c)(3) as the "Intraday Indicative Value," that reflects an estimated intraday value of the Fund's portfolio (including the Subsidiary's portfolio), will be disseminated. Moreover, the Intraday Indicative Value, available on the NASDAQ OMX Information LLC proprietary index data service [26] will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session.

The dissemination of the Intraday Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and will provide a close estimate of that value throughout the trading day.

Intra-day, executable price quotations on the exchange-traded assets held by the Fund and the Subsidiary, including futures contracts, options on futures contracts, ETFs, ETNs, closed-end funds and foreign and domestic equity securities are expected to be available on the exchange on which they are traded. Intra-day, executable price quotations on swaps, money market funds, forward contracts, U.S. government securities, cash and other cash equivalents, treasury inflation-protected securities, sovereign debt obligations of non-U.S. countries and repurchase agreements will be available from major broker-dealer firms. Intraday price information will also be available through subscription services, such as Bloomberg and Reuters. Additionally, the Trade Reporting and Compliance Engine ("TRACE") of the Financial Industry Regulatory Authority ("FINRA") will be a source of price information for certain fixed income securities held by the Fund.

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[24] Under accounting procedures to be followed by the Fund, trades made on the prior business day ("T") will be booked and reflected in NAV on the current business day ("T+1"). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[25] The IOPV will be based on the current value of the securities and other assets held by the Fund and the Subsidiary using market data converted into U.S. dollars at the current currency rates. The IOPV price will be based on quotes and closing prices from the securities' local market and may not reflect events that occur subsequent to the local market's close. Premiums and discounts between the IOPV and the market price may occur. The IOPV will not necessarily reflect the precise composition of the current portfolio of securities and assets held by a Fund at a particular point in time or the best possible valuation of the current portfolio. Therefore, the IOPV should not be viewed as a "real-time" update of a Fund's NAV, which will be calculated only once a day. The quotations of certain Fund holdings may not be updated during U.S. trading hours if such holdings do not trade in the United States.

[26] Currently, the NASDAQ OMX Global Index Data Service ("GIDS") is the NASDAQ OMX global index data feed service, offering real-time updates, daily summary messages, and access to widely followed indexes and Intraday Indicative Values for ETFs. GIDS provides investment professionals with the daily information needed to track or trade NASDAQ OMX indexes, listed ETFs, or third-party partner indexes and ETFs.

Investors will also be able to obtain the Fund's Statement of Additional Information ("SAI"), the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Fund's SAI and Shareholder Reports will be available free upon request from the Fund, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's Web site at *www.sec.gov.* Information regarding market price and volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association plans for the Shares. Quotation and last sale information for any underlying exchange-traded equity will also be available via the quote and trade service of their respective primary exchanges, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association plans. Quotation and last sale information for any underlying exchange-traded options will also be available via the quote and trade service of their respective primary exchanges. Quotation and last sale information for any underlying exchange-traded futures contracts will be available via the quote and trade service of their respective primary exchanges.

Information on the Morningstar Long/Flat Commodity Index℠ will be available on the Morningstar Indexes Web site (*www.indexes.morningstar.com*).

Initial and Continued Listing

The Shares will be subject to Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares. The Exchange represents that, for initial and/or continued listing, the Fund and the Subsidiary must be in compliance with Rule 10A–3 [27] under the Act. A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Nasdaq will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pauses under Nasdaq Rules 4120(a)(11) and (12). Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and other assets constituting the Disclosed Portfolio of the Fund and the Subsidiary; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq's existing rules governing the trading of equity securities. Nasdaq will allow trading in the Shares from 4:00 a.m. until 8:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in Nasdaq Rule 5735(b)(3), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is $0.01.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also the Financial Industry Regulatory Authority ("FINRA") on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[28] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows, and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

FINRA, on behalf of the Exchange, will communicate as needed regarding trading information it can obtain relating to the Shares, other exchange-traded securities and other assets held by the Fund and the Subsidiary, which include exchange-traded commodity-related equity securities, exchange-traded futures contracts, exchange-traded options on futures contracts, ETNs, ETFs and exchange-traded closed-end funds, with other markets and other entities that are members of the ISG [29] and FINRA may obtain trading information regarding trading in the Shares, and such exchange-traded securities and other assets held by the Fund and the Subsidiary from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, and such exchange-traded securities and other assets held by the Fund and the Subsidiary from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.

In addition, with respect to the exchange-traded futures contracts and options on futures contracts held, not more than 10% of the weight [30] of such futures contracts and options on futures contracts in the aggregate shall consist of instruments whose principal trading market is not a member of ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement. Not more than 10% of the equity securities (including shares of ETFs, closed-end funds, and commodity-related foreign and domestic equity securities) and ETNs in which the Fund may invest will be invested in securities that trade in markets that are not members of the ISG or are not parties to a comprehensive surveillance sharing agreement with the Exchange. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

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[27] *See* 17 CFR 240.10A–3.

[28] FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[29] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[30] To be calculated as the value of the contract divided by the total absolute notional value of the Fund's futures contracts.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (3) how and by whom the information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (4) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

Additionally, the Information Circular will reference that the Fund is subject to various fees and expenses. The Information Circular will also disclose the trading hours of the Shares of the Fund and the applicable NAV calculation time for the Shares. The Information Circular will disclose that information about the Shares of the Fund will be publicly available on the Fund's Web site.

Continued Listing Representations

All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act in general and Section 6(b)(5) of the Act in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Nasdaq Rule 5735. The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Adviser is affiliated with a broker-dealer and has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the Fund's portfolio. In addition, paragraph (g) of Nasdaq Rule 5735 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the open-end fund's portfolio.

The Fund's and the Subsidiary's investments will be consistent with the Fund's investment objective and although certain investments will have a leveraging effect on the Fund, the Fund will not seek leveraged returns. FINRA may obtain information via ISG from other exchanges that are members of ISG.

In addition, the Exchange may obtain information regarding trading in the Shares, other exchange-traded securities and other assets held by the Fund and the Subsidiary from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE. With respect to the futures contracts held, not more than 10% of the weight[31] of such futures contracts and options on futures contracts in the aggregate shall consist of instruments whose principal trading market is not a member of the ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement. Not more than 10% of the equity securities (including shares of ETFs and closed-end funds, and commodity-related foreign and domestic equity securities) and ETNs in which the Fund may invest will be invested in securities that trade in markets that not members of the ISG or are not parties to a comprehensive surveillance sharing agreement with the Exchange.

The Fund will invest up to 25% of its total assets in the Subsidiary as measured at each quarter-end of the Fund's fiscal year end. The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment). The Fund will use the fixed-income securities as investments and to collateralize the Fund's or the Subsidiary's commodity exposure on a day-to-day basis. The Fund may also invest directly in ETFs and exchange-traded closed-end funds, that provide exposure to commodities, equity securities and fixed income securities to the extent permitted under the 1940 Act.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

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[31] To be calculated as the value of the contract divided by the total absolute notional value of the Fund's futures contracts.

In addition, a large amount of information will be publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the Intraday Indicative Value, available on the NASDAQ OMX Information LLC proprietary index data service will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Regular Market Session. On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio of the Fund and the Subsidiary that will form the basis for the Fund's calculation of NAV at the end of the business day.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association plans for the Shares. Intra-day price information will be available through subscription services, such as Bloomberg and Reuters.

The Fund's Web site will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of the Fund will be halted under the conditions specified in Nasdaq Rules 4120 and 4121 or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to Nasdaq Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

As noted above, FINRA, on behalf of the Exchange, will communicate as needed regarding trading information it can obtain relating to the Shares, other exchange-traded securities and other assets held by the Fund and the Subsidiary with other markets and other entities that are members of the ISG and FINRA may obtain trading information regarding trading in the Shares, other exchange-traded securities and other assets held by the Fund and the Subsidiary from such markets and other entities.

In addition, the Exchange may obtain information regarding trading in the Shares, other exchange-traded securities and other assets held by the Fund and the Subsidiary from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Additionally, FINRA's TRACE will be a source of price information for certain fixed income securities held by the Fund. Furthermore, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares. For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change will facilitate the listing and trading of an additional type of actively-managed exchange-traded fund that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–086 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–086. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site *http://www.sec.gov/rules/sro.shtml*. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–086 and should be submitted on or before July 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Brent J. Fields,

Secretary.

[FR Doc. 2016–15454 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–10105; 34–78158; File No. 265–27]

SEC Advisory Committee on Small and Emerging Companies

AGENCY: Securities and Exchange Commission.

ACTION: Notice of meeting.

SUMMARY: The Securities and Exchange Commission Advisory Committee on Small and Emerging Companies is providing notice that it will hold a public meeting on Tuesday, July 19, 2016, in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC. The meeting will begin at 9:30 a.m. (EDT) and will be open to the public. The meeting will be webcast on the Commission's Web site at *www.sec.gov.* Persons needing special accommodations to take part because of a disability should notify the contact person listed below. The public is invited to submit written statements to the Committee. The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.

DATES: The public meeting will be held on Tuesday, July 19, 2016. Written statements should be received on or before July 15, 2016.

ADDRESSES: The meeting will be held at the Commission's headquarters, 100 F Street NE., Washington, DC. Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's Internet submission form (*http://www.sec.gov/info/smallbus/acsec.shtml*); or
- Send an email message to *rule-comments@sec.gov.* Please include File Number 265–27 on the subject line; or

Paper Statements

- Send paper statements to Brent J. Fields, Federal Advisory Committee Management Officer, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. 265–27. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method. The Commission will post all statements on the Advisory Committee's Web site (*http://www.sec.gov/spotlight/acsec-spotlight.shtml*).

Statements also will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All statements received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Julie Z. Davis, Senior Special Counsel, at (202) 551–3460, Office of Small Business Policy, Division of Corporation Finance, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: In accordance with Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C.-App. 1, and the regulations thereunder, Keith Higgins, Designated Federal Officer of the Committee, has ordered publication of this notice.

Dated: June 27, 2016.

Brent J. Fields,

Committee Management Officer.

[FR Doc. 2016–15509 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78151; File No. SR–OCC–2016–003]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to the Acceptance of Pass-Through Letters of Credit as a Form of Margin Asset

June 24, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 17, 2016, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by OCC. OCC filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(4)(ii) thereunder[4] so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change by OCC would amend OCC Rule 604 to permit pass-through letters of credit ("Pass-Through Letters of Credit") as a form of margin asset to satisfy margin obligations for futures, futures options, and commodity options positions (collectively referred to as "futures positions") held in segregated futures accounts and segregated futures professional accounts (collectively referred to as "segregated futures accounts") that are not eligible to hold positions in security futures.[5] Capitalized terms not defined herein have the same meaning as set forth in the OCC By-Laws and Rules.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The purpose of the proposed rule change is to amend OCC Rule 604 to permit Pass-Through Letters of Credit as a form of margin asset to satisfy margin obligations for positions held in segregated futures accounts that are not eligible to hold positions in security futures in order to provide futures market participants with the ability to deposit similar forms of collateral for segregated futures accounts at OCC as they could deposit at other futures clearinghouses. OCC Rule 604(c) allows Clearing Members to deposit letters of credit as a form of margin asset provided that such letters of credit meet the form prescribed by OCC and satisfy the robust eligibility requirements and risk controls enumerated under the Rule.[6] OCC currently accepts two party letters of credit as a form of margin asset under Rule 604(c), which are letters of credit issued by an OCC approved bank or trust on behalf of a Clearing Member, with OCC as beneficiary. Such letters of credit may be used by Clearing Members to meet margin obligations arising from positions held in any OCC account type.

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[32] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(4)(ii).

[5] *See* OCC By-Laws Article I, Section 1.S.(5) and (6) defining segregated futures accounts and segregated futures professional accounts.

Recently, certain futures market participants have inquired about using Pass-Through Letters of Credit as a form of margin asset at OCC. Pass-Through Letters of Credit are letters of credit issued on behalf of a third party (in this case, a customer of a Clearing Member) with a joint beneficiary structure that would allow the Clearing Member, as a joint beneficiary, to "pass through" the letter of credit directly to the clearinghouse, as joint beneficiary, and avoid the need for the Clearing Member to write its own letter of credit to the clearinghouse or to deposit cash margin on behalf of the customer. Pass-Through Letters of Credit are standard collateral vehicles accepted by other futures clearinghouses, particularly clearinghouses that provide clearance and settlement services for energy futures products. In order to provide OCC's futures commission merchant ("FCM") Clearing Members with the ability to deposit similar forms of collateral for segregated futures accounts as they could deposit at other futures clearinghouses, OCC proposes to add new Interpretation and Policy .10 to Rule 604 to permit its FCM Clearing Members to deposit Pass-Through Letters of Credit as margin assets to satisfy margin requirements for their futures customers. Pass-Through Letters of Credit would be permitted only to satisfy margin obligations for positions held in segregated futures accounts and would not be available as a form of margin asset to satisfy margin obligations for securities products.[7]

Pass-Through Letters of Credit would be subject to the same requirements and risk controls of Rule 604 as the currently accepted two party letters of credit. Pass-Through Letters of Credit deposited as margin assets would be based on the industry standard *Unified Clearing Group Uniform Letter of Credit Terms—(Pass-Through),* would be consistent with terms accepted by other futures clearinghouses, and would work similarly to the two party letters of credit currently used by OCC Clearing Members. Specifically, the issuing bank would be required to notify OCC of any changes to the terms of the letter of credit (and in certain cases, OCC would be required to affirmatively accept such changes) prior to such changes becoming effective. The issuing bank would be required to inform OCC in the event that a Clearing Member beneficiary wished to draw on the letter of credit, and all potential draws on the letter of credit, regardless of who initiates them, would be deposited directly into the FCM Clearing Member's OCC segregated futures account and would be subject to all of the rules and limitations surrounding the use and withdraw [sic] of margin funds under OCC's Rules. For these reasons, OCC believes that Pass-Through Letters of Credit, under the terms and restrictions described above, are similar to the existing two party letters of credit currently on deposit as margin assets at OCC and do not raise any unique risks to OCC.

In addition, existing Interpretations and Policies .10–.16 to Rule 604 would be renumbered but otherwise remain unchanged.

(2) Statutory Basis

OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,[8] and the rules thereunder applicable to OCC. As noted above, the form of Pass-Through Letters of Credit that would be accepted by OCC would have terms that work similarly to the two party letters of credit currently used by OCC Clearing Members and would be subject to the same restrictions and safeguards contained in Rule 604 and the Interpretations and Policies thereunder.[9] These safeguards include, among other things, that letters of credit deposited as margin assets have an unqualified commitment of the issuer to pay OCC within certain specified time periods, that all letters of credit must be irrevocable, and that OCC may draw upon a letter of credit at any time, whether or not the Clearing Member that deposited such letter of credit has been suspended by OCC or is in default with respect to any obligation to OCC. Moreover, the issuer and concentration limits for letters of credit deposited as margin assets are designed to ensure that OCC does not have excessive exposure to a particular issuing bank or to letters of credit generally as a form of margin asset. These requirements are designed to minimize the risk of loss or delay in OCC's access to funds payable under the letter of credit and reduce the likelihood that OCC would need to use the mutualized resources in its Clearing Fund to fulfill obligations arising from Clearing Members depositing letters of credit as a form of margin asset.

In addition to the restrictions and safeguards under Rule 604, the terms of the Pass-Through Letters of Credit would require that they effectively operate similarly to the two party letters of credit currently on deposit as margin assets at OCC. For example, OCC must be notified of (and in certain cases must affirmatively accept) any changes to the terms of the letter of credit, the issuing bank would be required to inform OCC in the case that the Clearing Member beneficiary wished to draw on the letter of credit, and all potential draws on the letter of credit, regardless of who initiates them, would be deposited directly into the FCM Clearing Member's segregated futures account.

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[6] Rule 604(c) requires, among other things, that: (i) Letters of credit must contain the unqualified commitment of the issuer to pay a specified sum of money to OCC within certain specified time periods; (ii) all letters of credit must be irrevocable; and (iii) OCC may draw upon a letter of credit at any time, whether or not the Clearing Member that deposited such letter of credit has been suspended by OCC or is in default with respect to any obligation to OCC, if OCC determines that such draw is advisable to protect OCC, other Clearing Members, or the general public. Moreover, if a Clearing Member deposits a letter of credit that indicates on its face that it is being deposited to serve as margin for the Clearing Member's customers' account or for a segregated futures account, such letter of credit shall not constitute margin for any other account maintained by the Clearing Member until such time as the issuing bank shall instruct OCC by amendment to the letter of credit stating that such letter of credit is not so restricted. *See* OCC Rule 604(c)(1) and (3). Letters of credit are also subject to specific eligibility standards for issuing banks and both Clearing Member and issuer concentration limits. Specifically, no more than 50% of a Clearing Member's margin on deposit at any given time may include letters of credit in the aggregate, and no more than 20% may include letters of credit issued by any one institution. Moreover, the total amount of letters of credit issued for the account of any one Clearing Member by a U.S. or Non-U.S. institution shall not exceed 15% of such institution's Tier 1 Capital. *See* OCC Rule 604, Interpretations and Policies .01, .02, and .04.

[7] In connection with the proposed rule change, OCC would implement procedural checks and verifications in its Collateral Services and Member Services Departments to ensure that (1) Pass-Through Letters of Credit would not be permitted to be allocated to a segregated futures account unless that account is not eligible to hold positions in security futures and (2) accounts holding Pass-Through Letters of Credit as a form of margin asset would not be enabled to hold positions in security futures.

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] *See supra* note 6 and related text.

For the reasons stated above, OCC believes that the proposed rule change is designed to assure the safeguarding of securities and funds which are in the custody or control of OCC or for which it is responsible in accordance with Section 17A(b)(3)(F) of the Act[10] and is reasonably designed to ensure that OCC holds margin assets in a manner that minimizes risk of loss or delay in its access to them, consistent with Rule 17Ad–22(d)(3).[11] The proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

(B) Clearing Agency's Statement on Burden on Competition

OCC does not believe that the proposed rule change would have any impact or impose any burden on competition[12] not necessary or appropriate in furtherance of the Act because it pertains solely to OCC's activities relating to the clearing of commodity futures products subject to the exclusive jurisdiction of the CFTC and therefore would not have any impact or impose any burden on competition in securities markets or any other market governed by the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing[13] pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and Rule 19b–4(f)(4)(ii) thereunder[15] because it effects a change in an existing service of OCC that (i) primarily affects the clearing operations of OCC with respect to products that are not securities, including futures that are not security futures and (ii) does not significantly affect any securities clearing operations of OCC or any rights or obligations of OCC with respect to securities clearing or persons using such securities-clearing service. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2016–003 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2016–003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.theocc.com/components/docs/legal/rules_and_bylaws/sr_occ_16_003.pdf.*

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–OCC–2016–003 and should be submitted on or before July 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Brent J. Fields,

Secretary.

[FR Doc. 2016–15455 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

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[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 17 CFR 240.17Ad–22(d)(3).

[12] 15 U.S.C. 78q–1(b)(3)(I).

[13] Notwithstanding the immediate effectiveness of the proposed rule change, implementation of this rule change is also contingent on it being deemed certified under CFTC Regulation § 40.6.

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(4)(ii).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78155; File No. SR–NYSEMKT–2016–64]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change for a Temporary Suspension of Those Aspects of Rules 36.20—Equities and 36.21—Equities That Would Not Permit Floor Brokers To Use Personal Portable Phone Devices on the Trading Floor Due to the Unavailability of Floor Broker Telephone Services

June 24, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 24, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a temporary suspension of those aspects of Rules 36.20—Equities and 36.21—Equities that would not permit Floor brokers to use personal portable phone devices on the Trading Floor due to the unavailability of Floor broker telephone services on June 24, 2016. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to temporarily suspend those aspects of Rules 36.20—Equities ("Rule 36.20") and 36.21—Equities ("Rule 36.21") that would not permit Floor brokers to use personal portable phone devices on the Trading Floor.[4] As proposed, all other aspects of Rule 36—Equities ("Rule 36") remain applicable and the temporary suspensions of the applicable Rule 36 requirements are in effect on June 24, 2016 only.[5]

On June 24, 2016, the third-party carrier that provides service for the wired phone lines for Floor brokers experienced an issue that affected the availability of those phone lines. This suspension of service only impacted the service for telephone service for Floor brokers and did not impact phone service for Designated Market Makers. The Exchange is working closely with the third-party carrier to restore such phone service.

Rules 36.20 and 36.21 govern the type of telephone communications that are approved for Floor brokers. Pursuant to Rule 36.20, Floor brokers may maintain a telephone line on the Trading Floor and use Exchange authorized and provided portable phones while on the Trading Floor. The use of such Exchange authorized and provided portable phones is governed by Rule 36.21. Because of the issues with the third-party carrier, Floor brokers are unable to reach their customers via their third-party carrier wired telephone lines. While Exchange-provided portable phones are operating, not all Floor brokers have Exchange-provided and authorized portable phones. However, the personal cell phones of Floor brokers are operational on the Trading Floor. The Exchange believes that because communications with customers is a vital part of a Floor broker's role as agent and therefore contributes to maintaining a fair and orderly market, during the period when the phone lines are non-operational, Floor brokers who do not have Exchange authorized and provided portable phones should be permitted to use personal cell phone devices in lieu of the non-operational wired phone lines.[6]

The Exchange therefore proposes to temporarily suspend the limitations in Rules 36.20 and 36.21 that permit Floor brokers to use only Exchange authorized and provided portable phones so that Floor brokers who do not have an Exchange authorized and portable phone may use personal cell phones on the Trading Floor. The Exchange proposes that pursuant to this temporary suspension, Floor brokers must provide the Exchange with the names of all Floor-based personnel who used personal portable phones during this temporary suspension period, together with the phone number and applicable carrier for each number. Floor broker member organizations must maintain in their books and records all cell phone records that show both incoming and outgoing calls that were made during the period that a personal portable phone was used on the Trading Floor. To the extent the records are unavailable from the third-party carrier, the Floor brokers must maintain contemporaneous records of all calls made or received on a personal portable phone while on the Trading Floor. As with all member organization records, such cell phone records must be provided to Exchange regulatory staff on request.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

In particular, because of issues experienced by a third-party phone carrier, wired phone lines are not functional. The Exchange believes that the proposed temporary suspensions from those aspects of Rule 36 that restrict Floor broker's use of personal portable phones on the Trading Floor removes impediments to and perfects the mechanism of a free and open market and national market system because the proposed relief will enable Floor brokers who do not have an Exchange authorized and provided portable phone to conduct their regular business, notwithstanding the ongoing issues with telephone service. The Exchange further believes that without the requested relief, Floor brokers would be compromised in their ability to conduct their regular course of business on the Trading Floor. In particular, for Floor brokers, because they operate as agents for customers, their inability to communicate with customers could compromise their ability to represent public orders on the Trading Floor.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on competition because the proposed change only impacts Floor brokers and has no change in operations for other market participants or other market centers. To the contrary, the Exchange believes that without the proposed relief, Floor brokers would be compromised in their ability to conduct their regular course of business on the Trading Floor, thereby placing a burden on the Floor brokers' ability to compete.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

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[4] Pursuant to Rule 6A—Equities, the Trading Floor is defined as the restricted-access physical areas designated by the Exchange for the trading of securities.

[5] The Exchange provided Floor brokers with notice of this rule filing, including the applicable recordkeeping and other requirements related to using personal cell phones during the temporary suspension of Rule 36.

[6] To the extent that the wired phone lines are operational, Floor brokers must use those phone lines rather than use a personal cell phone.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) under the Act[12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. In support of the request, the Exchange states that waiver the 30-day operative delay will allow the Exchange to invoke the relief immediately upon filing, which is necessary so that Floor brokers may be able to communicate with their customers on a day with significantly increased volumes of trading due both to the United Kingdom referendum vote to leave the European Union and the rebalancing of the Russell Investment Group indices after the close of trading on June 24, 2016. Based on the above, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because it will permit Floor brokers to remain in communication with customers while wired phone lines are unavailable. Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–64 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–64. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–64, and should be submitted on or before July 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–15500 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

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[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has determined to waive the five-day prefiling period in this case.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78152; File No. SR–NYSEArca–2016–90]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Temporarily Widen Price Collar Thresholds for the Core Open Auction and Trading Halt Auctions

June 24, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act"),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 24, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to temporarily widen price collar thresholds for the Core Open Auction and Trading Halt Auctions, which would be operative on June 24, 2016 only. The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to temporarily widen price collar thresholds for the Core Open Auction and Trading Halt Auctions, which would be operative for June 24, 2016 only.

On June 23, 2016, the United Kingdom ("UK") held a referendum vote to decide whether the UK should leave or remain in the European Union. The results of this vote were not made public until after the U.S. markets closed on June 23, 2016. Based on this referendum, the UK has voted to leave the European Union. As expected, this vote has resulted in an extraordinary level of global market activity on June 24, 2016, as the markets assess what the impact of the UK leaving the European Union will mean. This spike in market volatility has also impacted the U.S. equities markets, including pricing of Exchange Traded Products ("ETP"), the majority of which are listed on the Exchange.

Because of the extraordinary level of market volatility following the UK referendum vote, including in the U.S. ETP market, the Exchange believes that widening the Auction Collars for the Core Open Auction and Trading Halt Auctions for June 24, 2016 only would assist the Exchange in conducting fair and orderly auctions.

As set forth in Rule 7.35P(a)(10), the price collar thresholds for the Core Open Auction and Trading Halt Auctions are currently set at 10% for securities with an Auction Reference Price of $25.00 or less, 5% for securities with an Auction Reference Price greater than $25.00 but less than or equal to $50.00, and 3% for securities with an Auction Reference Price greater than $50.00.[4]

The Exchange proposes to apply Auction Collars of 10% for all Auction-Eligible Securities,[5] regardless of the Auction Reference Price. The Exchange believes that for securities priced greater than $25.00, the proposed wider price collar threshold will allow for additional price movements that is expected because of the extraordinary volatility in the market, while continuing to prevent auctions from occurring at prices significantly away from the applicable Auction Reference Price. The proposed 10% price collar threshold for the Core Open Auction is the same as currently used by the Nasdaq Stock Market LLC ("Nasdaq") for its opening crosses.[6]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

In particular, the Exchange believes that the impact of the UK vote to leave the European Union has resulted in extraordinary global market volatility, not seen in scale since August 24, 2015, and the U.S. ETP market is not immune. In response to this extraordinary market volatility, the Exchange believes that it would promote the protection of investors and the public interest to temporarily widen the price collar thresholds for the Core Open Auction and Trading Halt Auctions on June 24, 2016 only because it would promote fair and orderly auctions. The Exchange further believes that widening the price collar thresholds would remove impediments to and perfect the mechanism of a national market system because it is designed to allow for greater price movement, while at the same time preventing auction trades from occurring at prices significantly away from the applicable Auction Reference Price. Accordingly, investors would be protected from executions significantly away from the last sale in a security or other applicable reference price, but natural price fluctuations resulting from the market volatility would be permitted. In addition, the Exchange believes that widening the Auction Collars could reduce the possibility of securities triggering multiple trading pauses under the Regulation NMS Plan to Address Market Volatility.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to ensure a fair and orderly market by temporarily widening the price collar thresholds for the Core Open Auction and Trading Halt Auctions on a trading day with extraordinary market volatility due to the UK vote to leave the European Union, In addition, the proposed rule change is intended to be in effect for June 24, 2016 only to respond to unique events relating to UK referendum and therefore will not create a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section

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[4] The Auction Reference Price for the Core Open Auction is the midpoint of the Auction NBBO or, if the Auction NBBO is locked, the locked price. If there is no Auction NBBO, the prior trading day's Official Closing Price. The Auction Reference Price for the Trading Halt Auction is the last consolidated round-lot price of that trading day, and if none, the prior trading day's Official Closing Price. *See* NYSE Arca Equities Rule 7.35P(a)(8).

[5] For the Core Open Auction, Auction-Eligible Securities are all securities for which the Exchange is the primary listing market and UTP Securities designated by the Exchange. For the Trading Halt Auction, Auction-Eligible Securities are securities for which the Exchange is the primary listing market. *See* NYSE Arca Equities Rule 7.35P(a)(1)(A) and (B).

[6] *See* Nasdaq Rule 4752(d)(2)(E) and *http://www.nasdaqtrader.com/content/productsservices/trading/crosses/openclose_faqs.pdf*.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[11] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange stated that waiver of the operative delay would allow the Exchange to immediately implement the proposed rule change, thereby promoting the operation of a fair and orderly market on a day with extraordinary market volatility due to the UK referendum to leave the European Union. The Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2016–90 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–90. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–90, and should be submitted on or before July 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Brent J. Fields,

Secretary.

[FR Doc. 2016–15456 Filed 6–29–16; 8:45 am]

BILLING CODE 8011–01–P

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). The Exchange has requested that the Commission waive the requirement that the Exchange provide the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date on which the Exchange filed the proposed rule change pursuant to Rule 19b–4(f)(6)(iii). The Commission hereby grants this request.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14748]

Florida Disaster #FL–00117 Declaration of Economic Injury

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of Florida, dated 06/23/2016.

Incident: Violent Attack and Related Investigation.

Incident Period: 06/12/2016 and continuing.

Effective Date: 06/23/2016.

EIDL Loan Application Deadline Date: 03/23/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Orange.

Contiguous Counties:

Florida: Brevard, Lake, Osceola, Polk, Seminole, Volusia.

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for economic injury is 14748

The States which received an EIDL Declaration # are Florida.

(Catalog of Federal Domestic Assistance Number 59002)

Dated: June 23, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–15530 Filed 6–29–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14744 and #14745]

Texas Disaster Number TX–00472

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4272–DR), dated 06/11/2016.

Incident: Severe Storms and Flooding.

Incident Period: 05/26/2016 and continuing.

Effective Date: 06/22/2016.

Physical Loan Application Deadline Date: 08/10/2016.

Eidl Loan Application Deadline Date: 03/11/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of Texas, dated 06/11/2016 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans):
  Bastrop, Burleson, Eastland, Lee, Liberty, Stephens, Tyler.
Contiguous Counties: (Economic Injury Loans Only):
  Texas: Angelina, Brown, Callahan, Chambers, Comanche, Hardin, Jasper, Jefferson, Milam, Shackelford, Throckmorton, Young.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera Associate,

Administrator for Disaster Assistance.

[FR Doc. 2016–15531 Filed 6–29–16; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 9619]

Advisory Committee on International Economic Policy; Notice of Open Meeting

The Advisory Committee on International Economic Policy (ACIEP) will meet from 2:00 until 5:00 p.m. on Wednesday, July 27 in Washington, DC at the State Department, 2201 C Street NW. in conference Room 7516. The meeting will be hosted by the Assistant Secretary of State for Economic and Business Affairs, Charles H. Rivkin, and Committee Chair Paul R. Charron. The ACIEP serves the U.S. Government in a solely advisory capacity, and provides advice concerning topics in international economic policy. It is expected that during this meeting, the ACIEP subcommittees on sanctions policy and the Stakeholder Advisory Board will provide updates on their recent work.

This meeting is open to the public, though seating is limited. Entry to the building is controlled. To obtain pre-clearance for entry, members of the public planning to attend should *no later than Tuesday, July 19* provide their full name and professional affiliation to Alan Krill by email: *KrillA@state.gov.* Requests for reasonable accommodation should be made to Alan Krill before Tuesday, July 19. Requests made after that date will be considered, but might not be possible to fulfill.

For additional information, contact Alan Krill, Bureau of Economic and Business Affairs, at (202) 647–2231, or *KrillA@state.gov.*

Dated: June 24, 2016.

Alan Krill,

Designated Federal Officer, U.S. Department of State.

[FR Doc. 2016–15602 Filed 6–29–16; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice: 9617]

Culturally Significant Objects Imported for Exhibition Determinations: "The Art of the Qur'an: Treasures From the Museum of Turkish and Islamic Arts" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "The Art of the Qur'an: Treasures from the Museum of Turkish and Islamic Arts," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Arthur M. Sackler Gallery, Smithsonian Institution, Washington, DC, from on or about October 15, 2016, until on or about February 20, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: June 22, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–15398 Filed 6–29–16; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

Indexing the Annual Operating Revenues of Railroads

The Surface Transportation Board (STB) is publishing the annual inflation-adjusted index factors for 2015. These factors are used by the railroads to adjust their gross annual operating revenues for classification purposes. This indexing methodology ensures that railroads are classified based on real business expansion and not from the effects of inflation. Classification is important because it determines the extent to which individual railroads must comply with STB reporting requirements.

The STB's annual inflation-adjusted factors are based on the annual average Railroad's Freight Price Index which is developed by the Bureau of Labor Statistics (BLS). The STB's deflator factor is used to deflate revenues for comparison with established revenue thresholds.

The base year for railroads is 1991. The inflation index factors are presented as follows:

STB Railroad Inflation-Adjusted Index and Deflator Factor Table

Year	Index	Deflator
1991	409.50	[1] 100.00
1992	411.80	99.45
1993	415.50	98.55
1994	418.80	97.70
1995	418.17	97.85
1996	417.46	98.02
1997	419.67	97.50
1998	424.54	96.38
1999	423.01	96.72
2000	428.64	95.45
2001	436.48	93.73
2002	445.03	91.92
2003	454.33	90.03
2004	473.41	86.40
2005	522.41	78.29
2006	567.34	72.09
2007	588.30	69.52
2008	656.78	62.28
2009	619.73	66.00
2010	652.29	62.71
2011	708.80	57.71
2012	740.61	55.23
2013	764.19	53.53
2014	778.41	52.55
2015	749.22	54.60

[1] Ex Parte No. 492, Montana Rail Link, Inc., and Wisconsin Central Ltd., Joint Petition For Rulemaking With Respect To 49 CFR 1201, 8 I.C.C. 2d 625 (1992), raised the revenue classification level for Class I railroads from $50 million (1978 dollars) to $250 million (1991 dollars), effective for the reporting year beginning January 1, 1992. The Class II threshold was also raised from $10 million (1978 dollars) to $20 million (1991 dollars).

Effective Date: January 1, 2015.

For Further Information Contact: Pedro Ramirez 202–245–0333. [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339]

By the Board, William F. Huneke, Director, Office of Economics.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–15546 Filed 6–29–16; 8:45 am]

BILLING CODE 4915–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Actions Taken at June 16, 2016, Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: As part of its regular business meeting held on June 16, 2016, in Lancaster, Pennsylvania, the Commission took the following actions: (1) Approved or tabled the applications of certain water resources projects; (2) accepted a settlement in lieu of penalty from New Enterprise Stone & Lime Co., Inc.; and (3) took additional actions, as set forth in the **SUPPLEMENTARY INFORMATION** below.

DATES: June 16, 2016.

ADDRESSES: Susquehanna River Basin Commission, 4423 N. Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address. See also Commission Web site at *www.srbc.net.*

SUPPLEMENTARY INFORMATION: In addition to the actions taken on projects identified in the summary above and the listings below, the following items were also presented or acted upon at the business meeting: (1) Election of the member from the State of Maryland as Chair of the Commission and the member from the Federal Government as the Vice Chair of the Commission for the period of July 1, 2016, to June 30, 2017; (2) adoption of the FY2017–2018 Water Resources Program; (3) adoption of amendment of the *Comprehensive Plan for the Water Resources of the Susquehanna River Basin;* (4) adoption of FY2017 Regulatory Program Fee Schedule, effective July 1, 2016; (5) adoption of a preliminary FY2018 budget for the period July 1, 2017, to June 30, 2018; (6) adoption of the Policy for Sustainable Water Resources Fund; (7) adoption of the Guidelines for Terminating Review of a Project Application; (8) adoption of the Guidelines for Expiring Project Approvals; (9) approval/ratification of an agreement, purchase of information technology equipment, and several contracts; and (10) a report on delegated settlements with the following project sponsors, pursuant to SRBC Resolution 2014–15: Vestal Hills Hospitality, in the amount of $2,000; SWN Production Company LLC, in the amount of $7,000; Inflection Energy (PA), LLC, in the amount of $3,000; and Cedar Rock Materials Corp./Bower Quarry, in the amount of $3,000.

Compliance Matter

The Commission approved a settlement in lieu of civil penalty for the following project:

1. New Enterprise Stone & Lime Co., Inc., Valley Quarries, Inc.—Shippensburg Quarry, Shippensburg Borough, Cumberland County, Pa.—$30,000.

Project Applications Approved

The Commission approved the following project applications:

1. Project Sponsor and Facility: Black Bear Waters, LLC (Lycoming Creek), Lewis Township, Lycoming County, Pa. Renewal of surface water withdrawal of up to 0.900 mgd (peak day) (Docket No. 20120303).
2. Project Sponsor and Facility: Blossburg Municipal Authority, Bloss Township, Tioga County, Pa. Renewal of groundwater withdrawal of up to 0.288 mgd (30-day average) from Route 15 Well (Docket No. 20120304).
3. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Martins Creek), Harford Township, Susquehanna County, Pa. Surface water withdrawal of up to 0.500 mgd (peak day).
4. Project Sponsor and Facility: Todd and Gemma Campbell (Susquehanna River), Athens Township, Bradford County, Pa. Renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20120609).
5. Project Sponsor and Facility: Mount Joy Borough Authority, East Donegal Township, Lancaster County, Pa. Modification to increase withdrawal limit from Well 1 by an additional 0.073 mgd (30-day average), for a total Well 1 withdrawal limit of 1.300 mgd (30-day average) (Docket No. 20110617).
6. Project Sponsor: New Enterprise Stone & Lime Co., Inc. Project Facility: Burkholder Quarry, Earl Township, Lancaster County, Pa. Groundwater withdrawal of up to 0.005 mgd (30-day average) from Sump 4.
7. Project Sponsor: New Enterprise Stone & Lime Co., Inc. Project Facility: Burkholder Quarry, Earl and Ephrata Townships, Lancaster County, Pa. Modification to increase consumptive water use by an additional 0.07 mgd (peak day), for a total consumptive water use of up to 0.220 mgd (peak day) and to add an additional new source (Sump 4) (Docket No. 20040307).
8. Project Sponsor and Facility: Renovo Energy Center LLC (West Branch Susquehanna River), Renovo Borough, Clinton County, Pa. Surface water withdrawal of up to 0.612 mgd (peak day).
9. Project Sponsor and Facility: Renovo Energy Center LLC, Renovo Borough, Clinton County, Pa. Consumptive water use of up to 0.217 mgd (peak day).
10. Project Sponsor: SUEZ Water Pennsylvania Inc. Project Facility: Newberry System, Newberry Township, York County, Pa. Groundwater withdrawal of up to 0.108 mgd (30-day average) from the Coppersmith Well.
11. Project Sponsor: SUEZ Water Pennsylvania Inc. Project Facility: Newberry System, Newberry Township, York County, Pa. Groundwater withdrawal of up to 0.200 mgd (30-day average) from Conley 1 Well.

12. Project Sponsor and Facility: Sugar Hollow Trout Park and Hatchery, Eaton Township, Wyoming County, Pa. Renewal of groundwater withdrawal of up to 0.864 mgd (30-day average) from Wells 1, 2, and 3 (the Hatchery Wellfield) (Docket No. 20100913).

13. Project Sponsor and Facility: Tioga Downs Racetrack, LLC, Town of Nichols, Tioga County, N.Y. Groundwater withdrawal of up to 0.099 mgd (30-day average) from the Racetrack Well.

14. Project Sponsor and Facility: Tioga Downs Racetrack, LLC, Town of Nichols, Tioga County, N.Y. Consumptive water use of up to 0.099 mgd (peak day).

Project Applications Tabled

The Commission tabled action on the following project applications:

1. Project Sponsor and Facility: Elizabethtown Area Water Authority, Elizabethtown Borough, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.201 mgd (30-day average) from Well 1.

2. Project Sponsor and Facility: Elizabethtown Area Water Authority, Elizabethtown Borough, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.106 mgd (30-day average) from Well 3.

3. Project Sponsor and Facility: Elizabethtown Area Water Authority, Elizabethtown Borough, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.130 mgd (30-day average) from Well 4.

4. Project Sponsor and Facility: Elizabethtown Area Water Authority, Mount Joy Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.187 mgd (30-day average) from Well 8.

5. Project Sponsor and Facility: Elizabethtown Area Water Authority, Mount Joy Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.216 mgd (30-day average) from Well 9.

6. Project Sponsor: Exelon Generation Company, LLC. Project Facility: Muddy Run Pumped Storage Project, Drumore and Martic Townships, Lancaster County, Pa. Application for an existing hydroelectric facility.

7. Project Sponsor and Facility: Manbel Devco I, LP, Manheim Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 4.320 mgd (30-day average) from the Belmont Quarry.

Project Application Withdrawn by Project Sponsor

The following project sponsor withdrew its project application:

1. Project Sponsor and Facility: EQT Production Company (Pine Creek), Porter Township, Lycoming County, Pa. Application for surface water withdrawal of up to 1.000 mgd (peak day).

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: June 24, 2016.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2016–15427 Filed 6–29–16; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0069]

Request for Information: Nationally Uniform 911 Data System

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Notice; request for information.

SUMMARY: The development of a nationally uniform 911 data system, containing uniform data elements for all Computer Aided Dispatch (CAD) data, data associated with the operation of local and State 911 systems, and Extensible Markup Language (XML) schema (or technical equivalent) that would enable the collection, analysis and sharing of standardized administrative data, operational data, cost data and all Computer Aided Dispatch (CAD) data received, collected, processed, and transmitted during 911 calls; that would be developed and made available to all 911 Public Safety Answering Points (PSAPs) and 911 Authorities at the state and local levels. This nationally uniform 911 data system, once developed, would provide essential information to assist strategic planning, governance decisions, and improvements to the 911 system and its operation at all levels of government. These data would also be useful to private sector companies providing support services to local and state 911 agencies.

DATES: It is requested that comments on this announcement be submitted by September 28, 2016.

ADDRESSES: You may submit comments [identified by Docket No. NHTSA–2016–0069] through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Laurie Flaherty, National Highway Traffic Safety Administration, Office of Emergency Medical Services, (202) 366–2705, *LaurieFlaherty@dot.gov*, located at the United States Department of Transportation; 1200 New Jersey Avenue SE., NPD–400, Room W44–322, Washington, DC 20590. Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: DOT/NHTSA, on behalf of the National 911 Program, is seeking comments from all sources (public, private, governmental, academic, professional, associations, public interest groups, and other interested parties) on the idea of establishing a nationally uniform data system, to document PSAP 911 call data and the data related to the operation of 911 systems at all levels of government within the 911 community. A nationally uniform 911 data system was identified as a need by the Federal Communication Commission's (FCC's) Task Force on Optimal PSAP Architecture (TFOPA), in its final report, released January 29, 2016: "A National system enabling the collection and analysis of standardized administrative data, operational data, cost data and CAD data should be developed and made available to PSAPS and 911 Authorities, to provide essential information to substantiate planning decisions and improvements to assist in the migration towards NG911." Models for a nationally uniform data system exist in other disciplines, for example, the National Fire Operations Reporting System (N–FORS), *http://911perform.org* and the National EMS Information System (NEMSIS), *http://nemsis.org.* There are elements of these existing systems, in terms of their content and the processes used for their development, implementation, and operation, that could be adopted or adapted for use by the 911 community, in developing an analogous data system.

The purpose of this notice is to solicit comments and ideas on all aspects of the development, implementation and operation of a nationally uniform 911 data system from the broad 911 stakeholder community, including CAD vendors, CAD interface developers, PSAP managers, local and State 911 authorities and agencies, national professional 911 associations, other Federal agencies, academia, public interest groups, and any other interested parties; and to request responses to specific questions provided below. This is neither a request for proposals nor an invitation for bids.

Background

In January 2016, in partnership with the PSAP community, national professional 911 associations, all levels of government, and the private sector, the Task Force on Optimal PSAP Architecture (TFOPA) delivered its final report to the FCC. This document contains a collaborative vision for the future of optimal PSAPs and 911 systems in the United States. The document includes a section (5.9.2) entitled, "Findings and Considerations" recommending that, "a National system enabling the collection and analysis of standardized administrative data, operational data, cost data and CAD data should be developed and made available to PSAPS and 911 Authorities, to provide essential information to substantiate planning decisions and improvements to assist in the migration towards NG911."

This RFI request directly relates to this recommendation by seeking comment on specific potential components of a nationally uniform 911 data system that would be implemented and operated to bridge this identified gap, and the process that would be used to develop, implement and operate this data system.

Responses to the following questions are requested to help plan the development and creation of a nationally uniform 911 data system that would enable the collection and analysis of standardized PSAP data and operational 911 system data. Please provide references as appropriate.

1. What significant changes have occurred in 911 and PSAP related data systems at the national, State and local levels during the last ten years?

2. As a 911 stakeholder, how might the implementation of a nationally uniform 911 data system be most useful to you (*i.e.* planning, funding justification, strategic planning etc.)?

3. What are the most critical issues facing current use and future interconnection of PSAP CAD systems that could be addressed in the development of the nationally uniform 911 data system? Please be as specific as possible.

4. What CAD and/or PSAP and/or 911 system data do you presently collect and what additional data would be beneficial to assist with staffing, budgeting, testing, contract compliance, performance metrics, planning, governance, or quality improvement activities?

5. What kind of data elements would you consider as essential data related to information handled by telecommunicators and by CAD systems, in receiving and processing 911 calls, and transmitting information to emergency responders? Please be as specific as possible in listing examples.

6. What kind of data elements would you consider as essential data related to the administration and operation of a PSAP? Please be as specific as possible in listing examples.

7. What kind of data elements would you consider as essential data related to the administration and operation of a local/state 911 system? Please be as specific as possible in listing examples.

8. How could a nationally uniform 911 data system enhance collaboration among CAD/Records Management Systems (RMS), 911 authorities, the first responder community, and others?

9. How could the proposed data system promote community preparedness and resilience?

10. How could this proposed data system contribute to improved coordination at the local, regional, state and national levels?

11. What are your suggestions for the process that should be used in developing, implementing and/or operating a nationally uniform 911 data collection system? Please be as specific as possible.

12. What specific agencies/organizations/entities are essential to involve, as part of a collaborative group that develops, implements, and/or operates this data system?

13. In your opinion, what are the challenges that would have to be overcome, in implementing a nationally uniform 911 data system?

14. In your opinion, how would the existence of a nationally uniform 911 data system be beneficial in implementing Next Generation 911? Please be as specific as possible in providing examples.

15. Do you have any additional comments regarding this subject?

Issued on: June 23, 2016.

Jeffrey P. Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2016–15368 Filed 6–29–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

National Advisory Committee on Travel and Tourism Infrastructure; Solicitation for Committee Member Nominations

AGENCY: Department of Transportation.

ACTION: Notice.

SUMMARY: The Department of Transportation seeks member nomination for our National Advisory Committee on Travel and Tourism Infrastructure (NACTTI).

DATES: All nominations for NACTTI membership must be received on or before July 13, 2016.

ADDRESSES: All nomination material should be emailed to the Office of the Secretary at: *NACTTI@dot.gov,* or mailed to: U.S. Department of Transportation, Office of the Secretary, Attn: National Advisory Committee on Travel and Tourism Infrastructure, Room W86–483, 1200 New Jersey Ave. SE., Washington, DC 20590. Mailed applications must be postmarked by July 13, 2016.

Any person requiring accessibility accommodations should contact the Office of the Secretary at (202) 366–5903 or email the NACTTI Designated Federal Official at *NACTTI@dot.gov.*

FOR FURTHER INFORMATION CONTACT: NACTTI Designated Federal Official, at *NACTTI@dot.gov* or (202) 366–5903. Also visit the NACTTI Internet Web site at *www.transportation.gov/NACTTI.*

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to Section 1431 of the Fixing America's Surface Transportation (FAST) Act, the Secretary of Transportation established NACTTI on June 1, 2016, to provide information, advice, and recommendations to the Secretary on matters relating to the role of intermodal transportation in facilitating mobility related to travel and tourism activities. NACTTI will—

a. Advise the Secretary on current and emerging priorities, issues, projects, and funding needs related to the use of the intermodal transportation network of the United States to facilitate travel and tourism, taking into consideration existing data and recommendations on the U.S. transportation network including, but not limited, to DOT's 30-year Beyond Traffic framework.

b. Serve as a forum for discussion for travel and tourism stakeholders on transportation issues affecting interstate and interregional mobility of passengers;

c. Promote the sharing of information between the private and public sectors on transportation issues impacting travel and tourism;

d. Gather information, develop technical advice, and make recommendations to the Secretary on policies that improve the condition and performance of an integrated national transportation system that—

- Is safe, economical, and efficient; and
- maximizes the benefits to the United States generated through the travel and tourism industry;

e. Identify critical transportation facilities and corridors that facilitate and support the interstate and interregional transportation of passengers for tourism, commercial, and recreational activities;

f. Provide for development of measures of condition, safety, and performance for transportation related to travel and tourism;

g. Provide for development of transportation investment, data, and planning tools to assist Federal, State, and local officials in making investment decisions relating to transportation projects that improve travel and tourism; and

h. Address other issues of transportation policy and programs impacting the movement of travelers for tourism and recreational purposes, including by making legislative recommendations.

II. Committee Membership

NACTTI shall be composed of no more than 25 members, each of whom shall be appointed by the Secretary of Transportation for a 2-year term. The membership shall include public and private sector stakeholders involved in the transportation and travel and tourism industries including, but not limited to:

- The travel and tourism industry, product and service providers;
- Travel and tourism-related associations;
- Travel, tourism, and destination marketing organizations;
- The travel and tourism-related workforce;
- State tourism offices;
- State departments of transportation;
- Regional and metropolitan planning organizations;
- Local governments;
- Organizations with expertise in intermodal connectivity for travel and tourism; and
- Entities with expertise in public-private-partnerships (P3).

The Department shall establish a Chair and Vice Chair of the Advisory Committee from among those selected representatives.

III. Member Selection

A selection team comprised of representatives from several DOT operating administrations will review nomination packages. The selection team will make recommendations regarding membership to the Secretary of Transportation based on criteria including, but not limited to:

- Professional or academic expertise, experience, and knowledge;
- Stakeholder representation;
- Availability and willingness to serve; and
- Experience and skills working collaboratively on committees and advisory panels.

Additional factors which will be considered in the selection of NACTTI members include candidates' proven experience in the strategic development and management of travel, tourism, transportation-related or other service-related organizations; or the candidate's proven experience in promoting, developing, and implementing advertising, marketing, or financial programs for travel, tourism or transportation-related industries.

Priority may be given to a Chief Executive Officer, Executive Director, or President (or comparable level of responsibility) of a U.S. company, U.S. organization, or U.S. entity in the travel, tourism, or transportation sectors.

Each NACTTI member shall serve as the representative of a U.S. entity engaged in any of the above-listed activities.

Members shall serve in a representative capacity, representing the views and interests of their particular industry subsector. NACTTI members are not Special Government Employees, and will receive no compensation for their participation in NACTTI activities. Members participating in NACTTI meetings and events will be responsible for their travel, living and other personal expenses. Meetings will be held regularly and, to the extent practical, not less than twice annually, usually in Washington, DC.

IV. Nomination Information

For immediate consideration for membership, please provide the following information by the Wednesday, July 13, 2016, deadline to the address listed in the **ADDRESSES** section:

1. Name, title, and relevant contact information (including phone, fax, and email address) of the individual under consideration;
2. The company's, organization's, or entity's size, product or service line, and major markets in which the company, organization, or entity operates.
3. A letter of support or recommendation letter, on letterhead, from a company, union, trade or membership association, or non-profit organization containing a brief description of why the nominee should be considered for membership;
4. A one-page cover letter summarizing the applicant's unique experiences and qualifications, any professional and academic credentials, and the reason(s) why he or she would like to join NACTTI.
5. A resume for the individual under consideration.

Please do not send company, trade association, organization brochures or any other promotional information. Materials submitted should total five pages or less and must be in 12-point font, formatted in Microsoft Word or PDF. Should more information be needed, DOT staff will contact the nominee, obtain information from the nominee's past affiliations, or obtain information from publicly available sources, such as the Internet.

Dated: June 22, 2016.

Jenny T. Rosenberg,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2016–15285 Filed 6–27–16; 4:15 pm]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Notice Regarding Unauthorized Access to Customer Information

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently

valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, "Notice Regarding Unauthorized Access to Customer Information." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before August 1, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0227, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0227, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend the approval of the following information collection:

Title: Notice Regarding Unauthorized Access to Customer Information.

OMB Control No.: 1557–0227.

Description: Section 501(b) of the Gramm-Leach-Bliley Act (15 U.S.C. 6801) requires the OCC to establish appropriate standards for national banks relating to administrative, technical, and physical safeguards: (1) To insure the security and confidentiality of customer records and information; (2) to protect against any anticipated threats or hazards to the security or integrity of such records; and (3) to protect against unauthorized access to, or use of, such records or information that could result in substantial harm or inconvenience to any customer.

The Interagency Guidelines Establishing Information Security Standards, 12 CFR Part 30, Appendix B and Part 170, Appendix B (collectively, Security Guidelines), which implement section 501(b), require each entity supervised by the OCC (supervised institution) to consider and adopt a response program, as appropriate, that specifies actions to be taken when the supervised institution suspects or detects that unauthorized individuals have gained access to customer information.

The Interagency Guidance on Response Programs for Unauthorized Customer Information and Customer Notice (Breach Notice Guidance),[1] which interprets the Security Guidelines, states that, at a minimum, a supervised institution's response program should contain procedures for the following:

(1) Assessing the nature and scope of an incident and identifying what customer information systems and types of customer information have been accessed or misused;

(2) Notifying its primary Federal regulator as soon as possible when the supervised institution becomes aware of an incident involving unauthorized access to, or use of, sensitive customer information;

(3) Consistent with the OCC's Suspicious Activity Report regulations, notifying appropriate law enforcement authorities and filing a timely SAR in situations in which a Federal criminal violation requires immediate attention, such as when a reportable violation is ongoing;

(4) Taking appropriate steps to contain and control the incident in an effort to prevent further unauthorized access to, or use of, customer information, for example, by monitoring, freezing, or closing affected accounts, while preserving records and other evidence; and

(5) Notifying customers, as warranted.

This collection of information covers the notice provisions in the Breach Notice Guidance.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 20.

Total Estimated Annual Burden: 720 hours.

Frequency of Response: On occasion.

On April 12, 2016, the OCC issued a notice for 60 days regarding this collection, 81 FR 21666. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the information collection;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 27, 2016.

Mary Hoyle Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–15565 Filed 6–29–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Examination Questionnaire

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the renewal of an information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

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[1] 12 CFR Part 30, Appendix B, Supplement A.

The OCC is soliciting comment concerning renewal of its information collection titled, "Examination Questionnaire." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted by August 1, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0199, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0199, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval for the following information collection:

Title: Examination Questionnaire.

OMB Control No.: 1557–0199.

Affected Public: Businesses or other for-profit.

Type of Review: Extension of a currently approved collection.

Abstract:

The OCC provides each national bank or Federal savings association with an Examination Survey at the end of its supervisory cycle (12- or 18-month period). This information collection permits banks to assess the OCC's bank supervisory activities, including the:

- Effectiveness of OCC communications with the bank;
- Reasonableness of OCC requests for data and information;
- Quality of OCC decisionmaking during the exam process;
- Professionalism of OCC examining staff; and
- Responsiveness of OCC examiners.

The OCC developed the survey at the suggestion of the banking industry. Banking industry members expressed a desire to provide examination-related feedback to the OCC. The Comptroller of the Currency and OCC supervisory staff considered that suggestion and concurred. Further, the Comptroller of the Currency and OCC supervisory staff find this information collection to be an important tool for measuring OCC examination performance, designing more efficient and effective examinations, and targeting examiner training.

This information collection continues to formalize and promote a long-standing OCC program. The OCC always has given the institutions it supervises the opportunity to provide input regarding the examination process.

The Post Exit Survey is no longer being used and has been deleted from this collection.

Burden Estimates:

Estimated Number of Respondents: 1,212.

Estimated Number of Responses per Respondent per Year: 0.65.

Estimated Number of Responses: 788.

Estimated time per response: 10 minutes.

Estimated Annual Burden: 131 hours.

Comments: On April 4, 2016, the OCC published a notice for 60 days of comment concerning the collection, 81 FR 19287. One comment from an individual was received.

The commenter stated that the collection has no practical utility and is not necessary for the proper performance of the functions of the OCC because it does not generate objective assessments of the OCC's performance. The commenter suggested that the OCC should discuss why the potential for retaliation does not bias the results of the questionnaire and limit its usefulness.

The commenter believed that the practical utility of the questionnaire would be improved if the OCC explained why the questionnaire is not offered to the general public, bank customers, or other stakeholders and why it believes that banks provide a more accurate assessment of OCC effectiveness and quality.

The commenter believed that burden could be minimized by eliminating the questionnaire and instead soliciting feedback from bankers through regular outreach activities and called on the OCC to discuss in its final issuance why it has not been eliminated.

The commenter stated that the OCC improves the quality, utility, and clarity of the information when it attentively responds to all significant public comments before finalizing rules. The commenter also believed that when the OCC leaves unclear whether it considered comments, the public record is incomplete and the OCC creates the perception that it makes final decisions on rules without considering the data, views, and arguments of others.

The questionnaire attempts to receive feedback from bankers on supervision areas they find most valuable and areas that could be improved. The feedback is not meant to be an objective method of collection because it will be based on individual bank's experiences with the OCC staff and processes. The collection is voluntary, and the OCC's Ombudsman oversees the data and maintains confidentiality of individual bank responses to prevent retaliation.

Bankers are best equipped to respond to the survey given the objective of the questionnaire to measure OCC's performance and progress in improving the supervisory experience and agency communications. Bankers are direct stakeholders in the OCC's supervisory process and have ongoing contact with the OCC's staff and processes to assess the agency's performance. The general public, bank customers, and other stakeholders do not have direct interaction with the OCC's supervisory process to assess the agency's performance.

The questionnaire is administered in combination with feedback solicited directly from bankers through regular outreach activities. The questionnaire provides bankers the ability to provide candid feedback on the entire supervisory process while preserving their identity from the OCC staff that directly supervises the institutions.

Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Mary Hoyle Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–15594 Filed 6–29–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Community and Economic Development Entities, Community Development Projects, and Other Public Welfare Investments

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning its information collection titled, "Community and Economic Development Entities, Community Development Projects, and Other Public Welfare Investments." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before August 1, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0194, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0194, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: Community and Economic Development Entities, Community Development Projects, and Other Public Welfare Investments.

OMB Control No.: 1557–0194.

Description: This submission covers an existing regulation and revisions to the part 24, CD–1, National Bank Community Development Investments form contained in the regulation, pursuant to which a national bank may notify the OCC, or request OCC approval, of certain community development investments.

Section 24.5(a) provides that an eligible national bank may make an investment without prior notification to, or approval by, the OCC if the bank submits an after-the-fact notification of an investment within 10 days of making the investment.

Section 24.4(a) provides that a national bank may submit a written request or letter to the OCC to exceed the five percent limit for its aggregate, outstanding investments. The OCC may grant permission to the bank to make subsequent public welfare investments without prior notification to, or approval by the OCC, using the after-the-fact notification process consistent with Section 24.5(a).

Section 24.5(a)(5) provides that a national bank that is not an eligible bank, but that is at least adequately capitalized and has a composite rating of at least 3 with improving trends under the Uniform Financial Institutions Rating System, may submit a letter to the OCC requesting authority to submit after-the-fact notices of its investments.

Section 24.5(b) provides that if a national bank does not meet the requirements for after-the-fact notification, including if the bank's aggregate outstanding investments exceed the five percent limit, unless previously approved by the OCC for subsequent public welfare investments, the bank must submit an investment proposal to the OCC seeking permission to make the public welfare investment.

Type of Review: Regular.

Affected Public: Individuals; Businesses or other for-profit.

Estimated Number of Respondents: 1,100.

Estimated Total Annual Responses: 1,100.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 1,710 hours.

Comments: On April 4, 2016, the OCC published a notice for 60 days of comment concerning this collection, 81 FR 19289. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 27, 2016.

Mary Hoyle Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–15590 Filed 6–29–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 8288 and 8288–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8288, U.S. Withholding Tax Return for Disposition by Foreign Persons of U.S. Real Property Interests, and Form 8288–A, Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests.

DATES: Written comments should be received on or before August 29, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Kerry Dennis at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: U.S. Withholding Tax Return for Disposition by Foreign Persons of U.S. Real Property Interests (Form 8288) and Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests (Form 8288–A).

OMB Number: 1545–0902.

Form Number: 8288 and 8288–A.

Abstract: Internal Revenue Code section 1445 requires transferees to withhold tax on the amount realized from sales or other dispositions by foreign persons of U.S. real property interests. Form 8288 is used to report and transmit the amount withheld to the IRS. Form 8288–A is used by the IRS to validate the withholding, and a copy is returned to the transferor for his or her use in filing a tax return.

Current Actions: There are no changes being made to these forms at this time. The burden estimates below do not include estimates for business or individual filers. These estimates are for all other filers only as business estimates are reported under 1545–0123 and individual estimates are reported under 1545–0074.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals or households.

Form 8288:

Estimated Number of Respondents: 10,000.

Estimated Time per Respondent: 17 hr., 21 min.

Estimated Total Annual Burden Hours: 174,900.

Form 8288A:

Estimated Number of Respondents: 17,500.

Estimated Time per Respondent: 3 hr., 56 min.

Estimated Total Annual Burden Hours: 68,775.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 14, 2016.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2016–15459 Filed 6–29–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 6478

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 6478, Biofuel Producer Credit.

DATES: Written comments should be received on or before August 29, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Biofuel Producer Credit.

OMB Number: 1545–0231.

Form Number: Form 6478.

Abstract: Use Form 6478 to figure your section 40 biofuel producer credit. You claim the credit for the tax year in which the sale or use occurs. This credit consists of the second generation biofuel producer credit.

Current Actions: There are revisions being made to this form at this time.

Type of Review: Revisions of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,300.

Estimated Time per Respondent: 4 hours, 36 minutes.

Estimated Total Annual Burden Hours: 13,233.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 21, 2016.

Tuawana Pinkston,

IRS Clearance Officer.

[FR Doc. 2016–15453 Filed 6–29–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for e-Services Registration TIN Matching—Application and Screens for TIN Matching Interactive

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning e-Services registration TIN matching—application and screens for TIN matching interactive.

DATES: Written comments should be received on or before August 29, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: e-Services Registration TIN Matching—Application and Screens for TIN Matching Interactive.

OMB Number: 1545–1823.

Abstract: E-services is a system which permits the Internal Revenue Services to electronically communicate with third party users to support electronic filing and resolve tax administration issues for practitioners, payers, states and Department of Education Contractors. Registration is required to authenticate users that plan to access e-services products. This system is a necessary outgrowth of advanced information and communication technologies. TIN Matching is one of the products available through e-Services offered via the internet and accessible through the *irs.gov* Web site. TIN Matching allows a payer, or their authorized agent, who is required to file information returns for income subject to backup withholding to match TIN/Name combinations through interactive and bulk sessions. It is necessary for payers to apply online to use TIN Matching, and the information requested in the application process is used to validate them systemically as payers of the correct types of income.

Current Actions: This is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations and not-for-profit institutions.

Registration

Estimated Number of Responses: 1,560,000.

Estimated Average Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 520,000.

TIN Matching Application

Estimated Number of Responses: 18,825,000.

Estimated Average Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 3,670,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 21, 2016.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2016–15434 Filed 6–29–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Art Advisory Panel—Notice of Availability of Report of 2015 Closed Meetings

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice.

SUMMARY: Pursuant to 5 U.S.C. App. 2, section 10(d), of the Federal Advisory Committee Act, and 5 U.S.C. 552b, of the Government in the Sunshine Act, a report summarizing the closed meeting activities of the Art Advisory Panel during Fiscal Year 2015 has been prepared. A copy of this report has been filed with the Assistant Secretary for Management of the Department of the Treasury.

DATES: *Effective Date:* This notice is effective June 22, 2016.

ADDRESSES: The report is available for public inspection and requests for copies should be addressed to: Internal Revenue Service, Freedom of Information Reading Room, Room 1621, 1111 Constitution Avenue NW., Washington, DC 20224, Telephone number (202) 622–5164 (not a toll free number). The report is also available at *www.irs.gov.*

FOR FURTHER INFORMATION CONTACT: Maricarmen R. Cuello, AP:SO:AAS, Internal Revenue Service/Appeals, 51 SW., 1st Avenue, Room 1014, Miami, FL 33130, Telephone number (305) 982–5364 (not a toll free number).

SUPPLEMENTARY INFORMATION: It has been determined that this document is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis is, therefore, not required. Additionally, this document does not constitute a rule subject to the Regulatory Flexibility Act (5 U.S.C. Chapter 6).

Kirsten B. Wielobob,

Chief, Appeals.

[FR Doc. 2016–15452 Filed 6–29–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

June 24, 2016.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before August 1, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–1610.

Type of Review: Revision of a currently approved collection.

Title: Annual Return/Report of Employee Benefit Plan.

Form: Form 5500 and schedules.

Abstract: The Annual Return/Report of Employee Benefit Plan is an annual information return filed by employee benefit plans. The IRS uses this information for a variety of matters, including ascertainment whether a qualified retirement plan appears to conform to requirements under the Internal Revenue Code or whether the plan should be audited for compliance.

The Pension Benefit Guaranty Corporation (PBGC), the Department of Labor (DOL), and the Internal Revenue Service (IRS) work together to produce Form 5500 Annual Return/Report for Employee Benefit Plan and Form 5500–SF Short Form Annual Return/Report for Small Employee Benefit Plan (Form 5500 Series), through which the regulated public can satisfy the combined reporting/filing requirements applicable to employee benefit plans. The IRS produces Form 5500–SUP, a paper-only form, that is used by certain sponsors and administrators of retirement plans to satisfy certain of the reporting requirements of section 6058 of the Internal Revenue Code. Form 5500–SUP should be used only if certain IRS compliance questions are not answered electronically on the Form 5500 or Form 5500–SF.

BILLING CODE 4830–01–P

IRS Proposed Changes on the 2016 Form 5500 Series Returns

	Question on the 2015 Form 5500s	Form	Proposed 2016 Changes	Compliance and Use for
1	**a.** Name of trust **b.** Trust's EIN **c.** Name of trustee or custodian **d.** Trustee's or custodian's telephone number	Form 5500 Sch. H/I, 5500-SF, 5500-EZ, and 5500-SUP	a. Name of trust b. Trust's EIN c. Name of trustee or custodian d. Trustee's or custodian's telephone number	• This question was approved by OMB for the 2015 Form 5500 Series. • Requiring trust identifying information will assist the IRS in discharging its basic tax compliance and enforcement responsibilities with respect to tax-favored trusts. • This question was on former Schedule P up to 2006 where it had been approved in an information collection.
2	**a.** Preparer's name (including firm name, if applicable) and address (include room or suite number) **b.** Preparer's telephone number	Forms 5500, 5500-SF, 5500-EZ, and 5500-Sup.	**a.** Preparer's name (including firm name, if applicable) and address (include room or suite number) **b.** Preparer's telephone number	• This question was approved by OMB for the 2015 Form 5500 Series. • Information on Form 5500 Series preparers will assist the IRS in identifying preparers who have engaged in patterns of noncompliance. • Preparer questions were on Form 5500 through 2009 and after 2011 where they had been approved in an information collection.
3	a. Is the plan a 401(k) plan? ☐ Yes ☐ No b. If "Yes," how does the 401(k) plan satisfy the nondiscrimination requirements for employee deferrals and employer matching contributions (as applicable) under sections 401(k)(3) and 401(m)(2)? (See instructions) ☐ Design-based safe harbor method ☐ ADP/ACP test c. If ADP/ACP test is used, did the 401(k) plan perform ADP/ACP testing for the plan year using the "current year testing method" for nonhighly compensated	Form 5500 Sch R, 5500-SF, and 5500-SUP.	a. Is the plan a 401(k) plan? ☐ Yes ☐ No If "No," skip b. b. How did the plan satisfy the nondiscrimination requirements for employee deferrals under sections 401(k)(3) for the plan year? Check all that apply: ☐ Design-based safe harbor ☐ "Prior year" ADP test ☐ "Current year" ADP test ☐ N/A	• This question seeks basic information on the method by which a 401(k) plan satisfied the nondiscrimination requirements for employee deferrals. This information is fundamental to IRS's ability to monitor plans for compliance with the nondiscrimination rules.

	Question on the 2015 Form 5500s	Form	Proposed 2016 Changes	Compliance and Use for
	employees (Treas. Reg sections 1.401(k)-2(a)(2)(ii) and 1.401(m)-2(a)(2)(ii))? ☐ Yes ☐ No			
4	a. Check the box to indicate the method used by the plan to satisfy the coverage requirements under section 410(b): ☐ Ratio percentage test ☐ Average benefit test b. Does the plan satisfy the coverage and nondiscrimination tests of sections 410(b) and 401(a)(4) by combining this plan with any other plans under the permissive aggregation rules? ☐ Yes ☐ No	Form 5500 Sch R, 5500-SF, and 5500-SUP,	a. What testing method was used to satisfy the coverage requirements under section 410(b) for the plan year? Check all that apply: ☐ Ratio percentage test ☐ Average benefit test ☐ N/A b. Did the plan satisfy the coverage and nondiscrimination requirements of sections 410(b) and 401(a)(4) for the plan year by combining this plan with any other plan under the permissive aggregation rules? ☐ Yes ☐ No	• This question seeks basic information on the method by which a qualified plan satisfied the minimum coverage requirements on employee participation. This information is fundamental to IRS's ability to monitor plans for compliance with the minimum coverage rules. • This question was on former Schedule T where it had been approved in an information collection.
5	Were in-service distributions made during the plan year? ☐ Yes ☐ No If "Yes," enter amount ______	Form 5500 Sch H/I, 5500-SF, 5500-EZ, and 5500-SUP	Defined Benefit Plan or Money Purchase Pension Plan only: Were any distributions made during the plan year to an employee who attained age 62 and had not separated from service? ☐ Yes ☐ No	• This question should assist in the identification of whether distributions to employees are being made before otherwise permissible in a defined benefit or money purchase plan.
6	Did the plan trust incur unrelated business taxable income? ☐ Yes ☐ No ☐ N/A If Yes, enter amount ____	Form 5500, Sch H/I, 5500-SF, 5500-EZ, and 5500-SUP	Deleted	

	Question on the 2015 Form 5500s	Form	Proposed 2016 Changes	Compliance and Use for
7	a. Has the Plan been timely amended for all required law changes? b. Date the last Plan amendment/restatement for the required law changes was adopted__/__/____. Enter the applicable code ____ (See instructions for tax law changes and codes). c. If the plan sponsor is an adopter of a pre-approved master, prototype (M&P), or volume submitter plan that is subject to a favorable opinion or advisory letter from IRS, please enter the date of plan's last opinion or advisory letter__/__/___ and a letter serial number _______. d. If the plan is an individually-designed plan and received a favorable determination letter from IRS, please enter the date of plan's last favorable determination letter __/__/____.	Sch R Line 23a 5500-SF 17a 5500-SUP, Line 6a 5500-EZ, Line 13a	a. If the plan is a master and prototype plan (M&P) or volume submitter plan that received a favorable IRS opinion letter or advisory letter, enter the date of the letter _______/_______/_______ and the serial number ________________. b. If the plan is an individually-designed plan that received a favorable determination letter from the IRS, enter the date of the most recent determination letter ______/_______/_______.	- Whether and when a plan received a favorable opinion letter, advisory letter or determination letter from the IRS is a significant indicator of whether the form of the plan satisfies the qualification requirements under section 401(a).
8	Were required minimum distributions made to 5% owners who have attained age 70 ½ (regardless of whether or not retired), as required under section 401(a)(9)? ☐ Yes ☐ No ☐ N/A	Form 5500-SF and 5500-EZ only	Was any plan participant a 5% owner who had attained at least age 70 ½ during the prior plan year? ☐ Yes ☐ No	- This information identifies plans to which special rules apply that require minimum distributions to a participant regardless of whether he or she continues in employment. The information will assist the IRS to monitor plan compliance.
9	Is the Plan maintained in a U.S. territory (i.e., Puerto Rico (if no election under ERISA section 1022(i)(2)	Form 5500 Sch R 5500-SF and	Deleted	

	Question on the 2015 Form 5500s	Form	Proposed 2016 Changes	Compliance and Use for
	has been made), American Samoa, Guam, the Commonwealth of the Northern Mariana Islands or the U.S. Virgin Islands)?	5500-SUP.		

Affected Public: Businesses or other for-profits; Individuals or households; Not-for-profit institutions; and Farms.

Estimated Total Number of Respondents: 806,500.

Estimated Total Annual Burden Hours: 320,208.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–15532 Filed 6–29–16; 8:45 am]

BILLING CODE 4830–01–C

DEPARTMENT OF VETERANS AFFAIRS

Special Medical Advisory Group, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Special Medical Advisory Group will meet on September 1, 2016, at the Department of Veterans Affairs Central Office, 810 Vermont Ave. NW., Conference Room 830, Washington, DC 20420 from 8:00 a.m. to 4:00 p.m. ET. The meeting is open to the public.

The purpose of the Group is to advise the Secretary of Veterans Affairs and the Under Secretary for Health on the care and treatment of Veterans, and other matters pertinent to the Department's Veterans Health Administration (VHA).

The agenda for the meeting will include a review of MyVA Access, the Center for Compassionate Innovation/Fellowship Program, Strategic Partnerships and Rebuilding Relationships.

Thirty (30) minutes will be allocated for receiving oral presentations from the public. Members of the public may submit written statements for review by the Committee to Donna Wells-Taylor, Department of Veterans Affairs, Office of Specialty Care Services (10P4), Veterans Health Administration, 810 Vermont Avenue NW., Washington, DC 20420, or by email at *donna.wells-taylor@va.gov.*

Because the meeting is being held in a VA Central Office, a photo I.D. is required at the entrance as a part of the clearance process. Therefore, you should plan to arrive 15 minutes before the meeting begins to allow time for the clearance process. Any member of the public wishing to attend the meeting or seeking additional information should contact Ms. Donna Wells-Taylor at (202) 461–1025 or by email.

Dated: June 27, 2016.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2016–15576 Filed 6–29–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service, Scientific Merit Review Board; Amended Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Health Services Research and Development Service Scientific Merit Review Board will conduct in-person and teleconference meetings of its seven Health Services Research (HSR) subcommittees on the dates below from 8:00 a.m. to approximately 5:00 p.m. (unless otherwise listed) at the Hilton Crystal City, 2399 Jefferson Davis Highway, Crystal City, VA 22202 (unless otherwise listed):

- HSR 1—Health Care and Clinical Management on August 23–24, 2016;
- HSR 2—Behavioral, Social, and Cultural Determinants of Health and Care on August 23–24, 2016;
- HSR 3—Healthcare Informatics on August 24–25, 2016;
- HSR 4—Mental and Behavioral Health on August 23–24, 2016;
- HSR 5—Health Care System Organization and Delivery on August 24–25, 2016;
- HSR 6—Post-acute and Long-term Care on August 23, 2016;
- HSR 8—Randomized Program Evaluations from 8:00 a.m. to 12:00 p.m. on August 25, 2016; HSR 0—Precision Mental Health from 1:00 p.m. to 5:00 p.m. on August 25, 2016;
- CDA—Career Development Award Meeting on August 25–26, 2016; and
- NRI—Nursing Research Initiative from 1:00 p.m. to 5:00 p.m. on August 26, 2016.

** This notice is amended to reflect changes in one or more of the meetings (*i.e.,* date, time, etc.).

The purpose of the Board is to review health services research and development applications involving: The measurement and evaluation of health care services; the testing of new methods of health care delivery and management; and nursing research. Applications are reviewed for scientific and technical merit, mission relevance, and the protection of human and animal subjects. Recommendations regarding funding are submitted to the Chief Research and Development Officer.

Each subcommittee meeting of the Board will be open to the public the first day for approximately one half-hour at the start of the meeting on August 23 (HSR 6), August 23–24 (HSR 1, 2, 4), August 24–25 (HSR 3, 5), August 25 (HSR 0, 6, 8), August 25–26 (CDA), and August 26 (NRI) to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the subcommittee meetings may dial 1–800–767–1750, participant code 10443#.

The remaining portion of each subcommittee meeting will be closed for the discussion, examination, reference to, and oral review of the intramural research proposals and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to participate during the open portion of a subcommittee meeting should contact Ms. Liza Catucci, Administrative Officer, Department of Veterans Affairs, Health Services Research and Development Service (10P9H), 810 Vermont Avenue NW., Washington, DC 20420, or by email at *Liza.Catucci@va.gov.* For further information, please call Ms. Catucci at (202) 443–5797.

Dated: June 27, 2016.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2016–15520 Filed 6–29–16; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 126 June 30, 2016

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 414, and 494

Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413, 414 and 494

[CMS–1651–P]

RIN 0938–AS83

Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2017 as well as proposing to implement policies for coverage and payment for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also proposes to set forth requirements for the ESRD Quality Incentive Program, and proposes to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2020 and beyond and updates to programmatic policies for the PY 2018 and PY 2019 ESRD QIP. This rule also proposes to implement statutory requirements for bid surety bonds and state licensure for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). This rule also proposes to expand suppliers' appeal rights in the event of a breach of contract action by CMS. In particular, this rule proposes a revision to current regulations to provide that the appeals process is applicable to all breach of contract actions taken by CMS, rather than just for the termination of a competitive bidding contract. It also proposes changes to the methodologies for adjusting fee schedule amounts for DMEPOS using information from Competitive Bidding Programs and for submitting bids and establishing single payment amounts under the Competitive Bidding Programs for certain groupings of similar items with different features. Changes are also proposed to the methodology for establishing bid limits for items under the DMEPOS Competitive Bidding Programs. In addition, this rule also solicits comments on the impacts of coordinating Medicare and Medicaid Durable Medical Equipment for dually eligible beneficiaries. Finally, this rule announces a request for information related to the Comprehensive ESRD Care Model and future payment models affecting renal care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 23, 2016.

Application Submission Deadline: Applications must be received on or before July 15, 2016 for the Comprehensive ESRD Care Model.

ADDRESSES: In commenting, please refer to file code CMS–1651–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1651–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1651–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1810.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Janae James, (410) 786–0801 or Michelle Cruse, (410) 786–7540, for issues related to the ESRD PPS, and coverage and payment for renal dialysis services furnished to individuals with AKI.

Tamyra Garcia, (410) 786–0856, for issues related to the ESRD QIP.

Julia Howard, (410) 786–8645, for issues related to DMEPOS CBP and bid surety bonds, state licensure, and the appeals process for breach of DMEPOS CBP contract actions.

Anita Greenberg, (410) 786–4601, or Hafsa Vahora, (410) 786–7899, for issues related to competitive bidding and payment for similar DMEPOS items with different features and bid limits.

Kristen Zycherman, for issues related to DME access issues.

Tom Duvall, (410) 786–8887 or email *tom.duvall@cms.hhs.gov*, for issues related to the Comprehensive ESRD Care Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys)*, a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AAPM	Advanced Alternative Payment Model
ABLE	The Achieving a Better Life Experience Act of 2014
AHRQ	Agency for Healthcare Research and Quality
AKI	Acute Kidney Injury
AMCC	Automated Multi-Channel Chemistry
ANOVA	Analysis of Variance
APM	Alternative Payment Model
ARM	Adjusted Ranking Metric
ASP	Average Sales Price
ATRA	The American Taxpayer Relief Act of 2012
BEA	Bureau of Economic Analysis
BLS	Bureau of Labor Statistics
BMI	Body Mass Index
BSA	Body Surface Area
BSI	Bloodstream Infection
CB	Consolidated Billing
CBA	Competitive Bidding Area
CBP	Competitive Bidding Program
CBSA	Core Based Statistical Area
CCN	CMS Certification Number
CDC	Centers for Disease Control and Prevention
CEC	Comprehensive ESRD Care
CFR	Code of Federal Regulations
CHIP	The Children's Health Insurance Program
CIP	Core Indicators Project
CKD	Chronic Kidney Disease
CLABSI	Central Line Access Bloodstream Infections
CMS	Centers for Medicare & Medicaid Services
CPM	Clinical Performance Measure
CPT	Current Procedural Terminology
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
CY	Calendar Year
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics Supplies
DFR	Dialysis Facility Report
ESA	Erythropoiesis stimulating agent
ESCO	End-Stage Renal Disease Seamless Care Organization
ESRD	End-Stage Renal Disease
ESRDB	End-Stage Renal Disease Bundled
ESRD	PPS End-Stage Renal Disease Prospective Payment System
ESRD	QIP End-Stage Renal Disease Quality Incentive Program
FDA	Food and Drug Administration
HAIs	Healthcare-Acquired Infections
HCFA	Health Care Financing Administration

HCPCS Healthcare Common Procedure Coding System
HD Hemodialysis
HHD Home Hemodialysis
HHS Department of Health and Human Services
HCC Hierarchical Comorbidity Conditions
HRQOL Health-Related Quality of Life
ICD International Classification of Diseases
ICD–9–CM International Classification of Disease, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Disease, 10th Revision, Clinical Modification
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI IHS Global Insight
IIC Inflation-indexed charge
IPPS Inpatient Prospective Payment System
IUR Inter-unit reliability
KDIGO Kidney Disease: Improving Global Outcomes
KDOQI Kidney Disease Outcome Quality Initiative
KDQOL Kidney Disease Quality of Life
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large Dialysis Organization
MAC Medicare Administrative Contractor
MAP Medicare Allowable Payment
MCP Monthly Capitation Payment
MFP Multifactor Productivity
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MLR Minimum Lifetime Requirement
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA Medicare and Medicaid Extenders Act of 2010 Pub. L. 111–309
MSA Metropolitan statistical areas
NHSN National Healthcare Safety Network
NQF National Quality Forum
NQS National Quality Strategy
NAMES National Association of Medical Equipment Suppliers
OBRA Omnibus Budget Reconciliation Act
OMB Office of Management and Budget
PAMA Protecting Access to Medicare Act of 2014
PC Product category
PD Peritoneal Dialysis
PEN Parenteral and Enteral nutrition
PFS Physician Fee Schedule
PPI Producer Price Index
PPS Prospective Payment System
PSR Performance Score Report
PY Payment Year
QIP Quality Incentive Program
RCE Reasonable Compensation Equivalent
REMIS Renal Management Information System
RFA Regulatory Flexibility Act
SBA Small Business Administration
SFA Small Facility Adjuster
SPA Single Payment Amount
SRR Standardized Readmission Ratio
SSA Social Security Administration
STrR Standardized Transfusion Ratio
The Act Social Security Act
The Affordable Care Act The Patient Protection and Affordable Care Act
The Secretary Secretary of the Department of Health and Human Services
TPEA Trade Preferences Extension Act of 2015
TPS Total Performance Score
URR Urea reduction ratio
VAT Vascular Access Type
VBP Value Based Purchasing

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled prospective payment system for renal dialysis services furnished by ESRD facilities. This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2017. Section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), and section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) to an individual with AKI. Section 808(b) of TPEA amended section 1834 of the Act by adding a new paragraph (r) of the Act that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017.

3. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

This rule also proposes to set forth requirements for the ESRD QIP, including for payment years (PYs) 2018, 2019, and 2020. The program is authorized under section 1881(h) of the Social Security Act (the Act). The ESRD QIP is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS.

4. Durable Medical Equipment, Prosthetics, Orthotics Supplies (DMEPOS) Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions Proposals

This rule proposes to implement statutory requirements for Bid Surety Bonds and State Licensure. This rule also proposes to expand suppliers' appeal rights in the event of a breach of contract determination to allow suppliers to appeal any breach of contract action CMS takes, rather than just a termination action. To effect this policy change, we propose revisions to the regulations to provide that the appeals process applies to all breach of contract actions that CMS may take.

5. Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program and Fee Schedule Adjustments

This rule proposes to adjust the methodology for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from DMEPOS competitive bidding programs (CBPs), submitting bids and determining single payment amounts for certain groupings of similar items with different features under the DMEPOS CBPs, and establishing bid limits for individual items under the DMEPOS CBP.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2017:* The proposed CY 2017 ESRD PPS base rate is $231.04. This amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) (0.35 percent), and application of the wage index budget-neutrality adjustment factor (0.999552) as well as the application of the training budget-neutrality adjustment factor (0.999729). The proposed CY 2017 ESRD PPS base rate is $231.04 ($230.39 × 1.0035 × 0.999552 × 0.999729 = $231.04).
- *Annual update to the wage index and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD

facilities are located. For CY 2017, we are not proposing any changes to the application of the wage index floor and we propose to continue to apply the current wage index floor (0.400) to areas with wage index values below the floor.

- *Update to the outlier policy:* Consistent with our proposal to annually update the outlier policy using the most current data, we are proposing to update the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult and pediatric patients for CY 2017 using 2015 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries would increase from $62.19 to $67.44 and the MAP amount would increase from $39.20 to $39.92, as compared to CY 2016 values. For adult beneficiaries, the fixed-dollar loss amount would decrease from $86.97 to $83.00 and the MAP amount would decrease from $50.81 to $47.26. The 1 percent target for outlier payments was not achieved in CY 2015. We believe using CY 2015 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2017 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.
- *Payment for hemodialysis when more than 3 treatments are furnished per week:* We are proposing an equivalency payment for hemodialysis (HD) when more than 3 treatments are furnished in a week, similar to what is applied to peritoneal dialysis (PD). Specifically, we would calculate the total weekly amount that would be paid for 3 HD treatments per week and divide that number by the number of treatments furnished in a week when a beneficiary receives more than 3 HD treatments per week.
- *The home and self-dialysis training add-on payment adjustment:* We are proposing to increase the total number of hours of training by an RN for PD and HD that is accounted for by the home and self-dialysis training add-on payment adjustment (hereinafter referred to as the home dialysis training add-on). The current amount of the home dialysis training add-on is $50.16, which reflects 1.5 hours of training by a nurse per treatment. We propose to calculate the increase based on the average treatment times and weights based on utilization for each modality. We propose to use treatment times as proxies for the total time spent by nurses training beneficiaries for home or self-dialysis in calculating the proposed increase to the home dialysis training add-on, with the assumed hourly wage for a nurse providing dialysis training for 2017 being $35.93. Under this proposal, we would increase the hours of per-treatment training time provided by a nurse that is accounted for by the home dialysis training add-on to 2.66 hours.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are implementing the TPEA amendments to sections 1834(r) and 1861(s)(2)(F) by proposing to cover renal dialysis services furnished by renal dialysis facilities paid under section 1881(b)(14) of the Act to individuals with acute kidney injury. We are also proposing to pay ESRD facilities for renal dialysis services furnished to individuals with acute kidney injury at the amount of the ESRD PPS base rate, as adjusted by the ESRD PPS wage index. In addition, drugs, biologicals, and laboratory services that ESRD facilities are certified to furnish, but that are not renal dialysis services, may be paid for separately when furnished by ESRD facilities to individuals with AKI. In addition, because AKI patients are often under the care of a hospital, physician, or other practitioner, these providers could continue to bill Medicare for services outside of the ESRD PPS payment rate.

3. ESRD QIP

This rule proposes to set forth requirements for the ESRD QIP, including for payment years (PYs) 2018, 2019 and 2020.

Updating the Hypercalcemia Clinical Measure: Beginning with the PY 2018 ESRD QIP, we are proposing to update the technical specifications for the Hypercalcemia clinical measure so that they incorporate two substantive updates to the measure that were made during the measure maintenance process at National Quality Forum (NQF). First, plasma was added as an acceptable substrate in addition to serum calcium. Second, the denominator definition changed such that it now includes patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. These changes will ensure that the measure aligns with the NQF-endorsed measure and can continue to satisfy the requirements of the Protecting Access to Medicare Act (PAMA), which requires that the ESRD QIP include in its measure set measures (outcomes-based, to the extent feasible), that are specific to the conditions treated with oral-only drugs.

Proposed New Requirements for the PY 2019 ESRD QIP: For PY 2019 and future payment years, we are proposing to reintroduce the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure back into the ESRD QIP measure set. Additionally, for PY 2019 and future payment years, we are proposing to create a new NHSN BSI Measure Topic which will consist of the proposed NHSN Dialysis Event Reporting Measure and the existing NHSN BSI Clinical Measure. We are also proposing to establish a new Safety Measure Domain, which will be separate from, and in addition to, the existing Clinical Measure and Reporting Measure Domains for the purposes of scoring in the ESRD QIP. The proposed Safety Measure Domain will initially consist of the proposed NHSN BSI Measure Topic.

PY 2020 Measure Set: For PY 2020 and future payment years, we are proposing to replace the Mineral Metabolism Reporting Measure with the proposed Serum Phosphorus Reporting Measure because replacing this measure is consistent with our intention to increasingly rely on CROWNWeb as the data source used to calculate measures in the ESRD QIP. Additionally, we are proposing to adopt two new measures: (1) The Standardized Hospitalization Ratio (SHR) Clinical Measure and (2) the Ultrafiltration Rate Reporting Measure.

Updates to Weighting for the Clinical Measure Domain, the Reporting Measure Domain and the Proposed Safety Measure Domain: With the proposed addition of the Safety Measure Domain into the ESRD QIP, we are proposing changes to the weighting of the Clinical Measure Domain, the Reporting Measure Domain, and we are proposing to establish weights for the proposed Safety Measure Domain for PY 2019 and for PY 2020.

Specifically, for PY 2019 we are proposing to assign 15 percent of a facility's TPS to the proposed Safety Measure Domain, 75 percent of the TPS to the Clinical Measure Domain and 10 percent to the Reporting Measure Domain. To accommodate the removal of the Safety Subdomain from the Clinical Measure Domain, we are proposing to adjust individual measure weights for the measures that remain in the Clinical Measure Domain. For PY 2020, we are proposing to reduce the weight of the Safety Measure Domain to 10 percent of a facility's Total Performance Score. This modification, in combination with the proposed addition of the SHR measure necessitates further adjustments to individual measure weights in the Clinical Measure Domain.

Data Validation: In section IV.C.8 of this proposed rule, we set forth the updates we are proposing to make to the data validation program in the ESRD QIP. For PY 2019, we are proposing to continue the pilot validation study for validation of CROWNWeb data. Under this continued validation study, we are proposing to continue using the same methodology used for the PY 2017 and PY 2018 ESRD QIP. We will sample the same number of records (approximately 10 per facility) from the same number of facilities (that is, 300) during CY 2017. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

For PY 2019, we are also proposing to increase the size of the NHSN BSI Data Validation study. Specifically, we propose to randomly select 35 facilities to participate in an NHSN dialysis event validation study for two quarters of data reported in CY 2017. A CMS contractor will send these facilities requests for medical records for all patients with "candidate events" during the evaluation period, as well as randomly selected patient records. Each facility selected will be required to submit 10 records total to the validation contractor. The CMS contractor will utilize a methodology for reviewing and validating the candidate events and will analyze those records to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. Information from the validation study may be used to develop a methodology to score facilities based on the accuracy of their reporting of the NHSN BSI measure.

4. DMEPOS Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for a Breach of DMEPOS Competitive Bidding Program Contract Action Proposals.

This proposed rule proposes to implement statutory requirements for the DMEPOS CBP for bid surety bonds and state licensure. In addition, we are proposing to define the term "bidding entity" for purposes of the DMEPOS CBP. We also propose to expand suppliers' appeal rights in the event of a breach of contract determination to allow suppliers to appeal any breach of contract action CMS takes, rather than just a termination action. We propose revisions to the regulations to extend the appeals process to all competitive bidding breach of contract actions.

- A bidding entity must obtain a bid surety bond from an authorized surety on the Department of the Treasury's Listing of Certified Companies, submit proof of the surety bond by the deadline for bid submission, and the bond must meet certain specifications. We are proposing to define the term "bidding entity" to mean the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.

- If the bidding entity is offered a contract for any product category for a competitive acquisition area (herein referred to as a "Competitive Bidding Area" or "CBA"), and its composite bid for such product category and area is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category/CBA combination (herein also referred to as "competition"), and the entity does not accept the contract offered, the entity's bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective authorized surety. If the forfeiture conditions are not met, the bond liability will be returned to the bidding entity. Bidding entities that provide a falsified bid surety bond will be prohibited from participation in the DMEPOS CBP for the current round of the CBP in which they submitted a bid and also from bidding in the next round of the CBP. Bidding entities that provide a falsified bid surety bond will also be referred to the Office of Inspector General and Department of Justice for further investigation.

- We propose to conform the language of our regulation at 42 CFR 414.414(b)(3) to the language of section 1847(b)(2)(A)(v) of the Act, as added by section 522 of MACRA, which requires bidding entities to meet applicable State licensure requirements in order to be eligible for a DMEPOS CBP contract. We note, however, that this does not reflect a change in policy as CMS already has a regulation in place to require suppliers to meet applicable State licensure requirements.

- Appeals process for breach of DMEPOS CBP contract actions would extend the appeals process, specified in § 414.423, that currently only applies to contract terminations to all breach of contract actions taken by CMS and specified in § 414.422(g)(2). We propose to revise § 414.422(g)(2) to eliminate certain breach of contract actions for the reasons explained below. We also propose to revise 414.423(l) to describe the effects of certain breach of contract actions CMS may take.

5. DMEPOS Competitive Bidding Program and Fee Schedule Adjustments

This rule proposes to set forth requirements for the CBP and Fee Schedule Adjustments.

- Methodologies for Adjusting DMEPOS Fee Schedule Amounts for Certain Groupings of Similar Items with Different Features using Information from Competitive Bidding Programs: Within the Healthcare Common Procedure Coding System (HCPCS), there are many instances where there are multiple codes for an item that are distinguished by the addition of a feature (for example, non-powered versus powered mattress, Group 1 versus Group 2 power wheelchair, pump without alarm versus pump with alarm, walker without wheels versus walker with wheels, etc.) Under CBPs, the code with the higher utilization (typically the item with additional features and higher fee schedule amounts) receives a higher weight and the bid for this item has a greater impact on the supplier's composite bid than the bids for the less frequently used codes. This is resulting in price inversions where the single payment amounts (SPAs) for the item without the feature are higher than the SPAs for the item with the feature. This could lead to a program vulnerability by shifting beneficiaries from products with features to less appropriate products without the features because the latter receives higher payment under competitive bidding. We are proposing to limit SPAs for items without a feature to the weighted average of the SPAs for the items both with and without the feature prior to using the SPAs in adjusting the fee schedule amounts for certain groupings of similar items specified below. The item weights would be the same weights used in calculating the composite bids under the CBP.
- Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items with Different Features under the DMEPOS CBP: This proposal addresses the price inversions under competitive bidding to prevent situations where beneficiaries receive items with fewer features at a higher price than items with more features. In addition to affecting the appropriateness of items supplied to beneficiaries, these price inversions also undermine the CBP and diminish the savings intended from implementation of the program. We are proposing to revise the provisions of § 414.408 to add a lead item bidding methodology where all of the HCPCS codes for similar items with different features would be

grouped together and would be priced relative to the bid for the lead in order to prevent price inversions under the DMEPOS CBPs. We are proposing this as an alternative to the current bidding methodology that CMS would be able to apply to situations where groupings of similar items have resulted in price inversions based on past experience. This methodology would only replace the current method of bidding for select groupings of similar items within product categories.

- Bid Limits for Individual Items under the DMEPOS CBP: Current regulations require that bids submitted by suppliers under the CBP be lower than the amount that would otherwise apply (that is, the fee schedule amount). This ensures that total payments expected to be made to contract suppliers in a CBA are less than the total amounts that would otherwise be paid, which is a condition mandated by the section 1847(b) of the Act for awarding contracts under the program in an area. Beginning in 2016, the fee schedule amounts for DMEPOS items and services are adjusted based on information from the CBPs. We indicated in the final rule (79 FR 66232), which was published in the **Federal Register** on November 6, 2014, that these adjusted fee schedule amounts become the bid limits for future competitions (79 FR 66232). We have heard concerns that as the amounts paid under CBPs decline, this may ultimately make it difficult for suppliers to bid below the adjusted fee schedule amounts and accept contract offers at the median bid level. To avoid this situation and enhance the long term viability of the CBPs, we are proposing to limit bids for future competitions to the fee schedule amounts that would otherwise apply as if CBPs had not been implemented and prior to making adjustments to the fee schedule amounts using information from CBPs. This would allow suppliers to take into account both decreases and increases in costs in determining their bids, while ensuring that payments under the CBPs do not exceed the amounts that would otherwise be paid had the DMEPOS CBP not been implemented.

C. Summary of Costs and Benefits

In section XVI.A of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section XVI.B.1 of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2017 compared to estimated payments in CY 2016. The overall impact of the CY 2017 changes is projected to be a 0.5 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.7 percent increase in payments compared with freestanding facilities with an estimated 0.5 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately $50 million from CY 2016 to CY 2017. This reflects a $30 million increase from the payment rate update and a $20 million increase due to the updates to the outlier threshold amounts. As a result of the projected 0.5 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.5 percent in CY 2017, which translates to approximately $10 million.

2. Impacts of the Proposed Coverage and Payment for Renal Dialysis Services Furnished to Individuals with AKI

We anticipate an estimated $2.0 million being redirected from hospital outpatient departments to ESRD facilities in CY 2017 as a result of some AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus continuing to receive those services in the hospital outpatient setting.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the ESRD QIP will be approximately $15.5 million in PY 2019 and $113 million in PY 2020. The $15.5 million figure for PY 2019 includes costs associated with the collection of information requirements, which we estimate will be approximately $21 thousand.[1] For PY 2020, we estimate that ESRD facilities will experience an aggregate impact of approximately $113 million as a result of the PY 2020 ESRD QIP.

The ESRD QIP will continue to incentivize facilities to provide high-quality care to beneficiaries.

4. Impacts of the DMEPOS Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for a Breach of DMEPOS Competitive Bidding Program Contract Actions Proposals

The DMEPOS CBP bidding entities will be impacted by the bid surety bond requirement as they will be required to purchase a bid surety bond for each CBA in which they are submitting a bid. The state licensure requirement will have no new impact on the supplier community because this is already a Medicare DMEPOS supplier requirement and the appeals process for a breach of a DMEPOS CBP contract action(s) is expected to have a beneficial, positive impact on suppliers.

Overall, the bid surety bond requirement may have a positive financial impact on the program as CMS anticipates that the requirement will encourage all bidding entities to submit substantiated bids. However, there will be an administrative burden for implementation of the bid surety bond requirement for CMS. The state licensure and appeals process for breach of DMEPOS CBP contract actions proposals will have minimal administrative costs.

We do not anticipate that the proposed DMEPOS CBP regulations for bid surety bonds, state licensure, and the appeals process for breach of DMEPOS CBP contract actions will have an impact on Medicare beneficiaries.

5. Impacts of the Proposed DMEPOS Competitive Bidding Program and Fee Schedule Adjustments Proposals

The overall economic impact for the proposed changes to the DMEPOS CBPs and Fee Schedule Adjustments would be about $20 million dollars in savings to the Part B Trust Fund over five years beginning January 1, 2017. The savings is a result of avoiding price inversions. This proposal should have a minor impact on the suppliers of CBAs and in the non-competitive bidding areas (non-CBAs). Beneficiaries would have lower coinsurance payments and receive the most appropriate items as a result of this proposal.

II. Calendar Year (CY) 2017 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning with calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

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[1] We note that the aggregate impact of the PY 2019 ESRD QIP was included in the CY 2016 ESRD PPS Final Rule (80 FR 68971). The previously finalized aggregate impact of $15.5 million reflects the PY 2019 estimated payment reductions and the collection of information requirements finalized in the PY 2019 ESRD QIP Final Rule.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93). Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CYs 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR 413.171 and our other payment policies are included in regulations in subpart H of 42 CFR part 413. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area (BSA), low body mass index (BMI), onset of dialysis, four co-morbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (42 CFR 413.235(a) and(b)).

In addition, the ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (42 CFR 413.232). The second adjustment reflects differences in area wage levels developed from Core Based Statistical Areas (CBSAs) (42 CFR 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (42 CFR 413.233).

The ESRD PPS allows for a training add-on for home and self-dialysis modalities (42 CFR 413.235(c)). Lastly, the ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (42 CFR 413.237).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 6, 2015, we published in the **Federal Register** a final rule (80 FR 68968 through 69077) titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule" (hereinafter referred to as the CY 2016 ESRD PPS final rule). In that final rule, we made a number of routine updates to the ESRD PPS for CY 2016, refined the ESRD PPS case-mix adjustments, implemented a drug designation process, updated the outlier policy, and made additional policy changes and clarifications. Specifically, in that rule, we finalized the following:

- *ESRD PPS refinement:* In accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. We revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. In addition, we removed two comorbidity category payment adjustments (bacterial pneumonia and monoclonal gammopathy). Because we conducted an updated regression analysis to enable us to analyze and revise the case-mix payment adjustments, we also revised the low-volume payment adjustment (LVPA) and implemented a new rural adjustment based on that regression analysis. We finalized new patient and facility-level adjustment factors and also revised the geographic proximity eligibility criterion for the LVPA and removed grandfathering from the criteria for the adjustment.
- *Drug designation process:* In accordance with section 217(c) of

PAMA, we implemented a drug designation process for: (1) Determining when a product is no longer an oral-only drug, and (2) including new injectable and intravenous renal dialysis service drugs and biologicals into the bundled payment under the ESRD PPS.

- *Update to the ESRD PPS base rate for CY 2016:* The CY 2016 ESRD PPS base rate was finalized at $230.39. This amount reflected a reduced market basket percentage rate of increase as required by section 1881(b)(14)(F)(i)(I) (0.15 percent), application of the wage index budget-neutrality adjustment factor (1.000495), and a refinement budget-neutrality adjustment factor (0.960319). The final CY 2016 ESRD PPS base rate was $230.39 ($239.43 × 1.000495 × 1.0015 × 0.960319 = $230.39).
- *Annual update to the wage index and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2016, we completed the 2-year transition to both the updated CBSA delineations and the labor-related share to which the wage index is applied (50.673 percent). In addition, we computed a wage index budget-neutrality adjustment factor of 1.000495, which was applied to the ESRD PPS base rate. We finalized the continuation of the application of the current wage index floor (0.4000) to areas with wage index values below the floor.
- *Update to the outlier policy:* We update the outlier policy using the most current data. Specifically, we updated the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult and pediatric patients for CY 2016 using 2014 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries increased from $54.35 to $62.19 and the MAP amount decreased from $43.57 to $39.20, as compared to CY 2015 values. For adult beneficiaries, the fixed-dollar loss amount increased from $86.19 to $86.97 and the MAP amount decreased from $51.29 to $50.81. The 1.0 percent target for outlier payments was not achieved in CY 2014 (0.8 percent rather than 1.0 percent). We believe using CY 2014 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2016 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.

B. Provisions of the Proposed Rule

1. Payment for Hemodialysis When More Than 3 Treatments Are Furnished per Week

a. Background

Since the composite rate payment system was implemented in the 1980s, we have reimbursed ESRD facilities for up to three hemodialysis (HD) treatments per week and only paid for weekly dialysis treatments beyond this limit when those treatments were medically justified due to the presence of specific comorbid diagnoses that necessitate additional dialysis treatments (see paragraph (d) of this section). When we implemented the ESRD PPS in 2011, we adopted a per treatment unit of payment (75 FR 49064). This per treatment unit of payment is the same base rate that is paid for all dialysis treatment modalities furnished by an ESRD facility (HD and the various forms of peritoneal dialysis (PD)) (75 FR 49115). Consistent with our policy since the composite rate payment system was implemented in the 1980s, we also adopted the 3-times weekly payment limit for HD under the ESRD PPS (74 FR 49931). When a beneficiary's plan of care requires more than 3 weekly dialysis treatments, whether HD or daily PD, we apply payment edits to ensure that Medicare payment on the monthly claim is consistent with the 3-times weekly dialysis treatment payment limit. Thus, for a 30-day month, payment is limited to 13 treatments, and for a 31-day month payment is limited to 14 treatments.

Because PD is typically furnished more frequently than HD, we calculate HD-equivalent payment rates for PD that are based on the ESRD PPS base rate per treatment. To do this, we adjust the base rate by any applicable patient- or facility-level adjustments, and then multiply the adjusted base rate by 3 (the weekly treatment limit), and divide this number by 7. This approach creates a per treatment amount that is paid for each day of PD treatment and that complies with the monthly treatment payment limit. With regard to HD, because we do not have a payment mechanism for the ESRD facility to bill and be paid for every treatment furnished when more than 3 treatments are furnished per week (for example, how they bill daily for PD), we apply edits to the monthly claim so that in total for the month (as described above) Medicare does not make payment for more than 3 weekly HD treatments. In the situation where an ESRD facility bills for more than 3 weekly HD treatments (or more than 13 or 14 for the month, depending on the days in the month) without medical justification, we deny payment for the additional HD treatments. We calculate HD-equivalent payments for PD so that the amount we pay for dialysis is modality-neutral. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49115), we chose not to use dialysis modality as a payment variable when we developed the ESRD PPS because utilizing one dialysis-neutral payment resulted in a slightly higher payment for PD than a modality-specific payment, which we believed would encourage home dialysis, which is typically PD.

In recent years, ESRD facilities have increasingly begun to offer HD where the standard treatment regimen exceeds 3 treatments per week. At the same time, we observed variation in how MACs processed claims for HD treatments exceeding three treatments per week, resulting in payment of more than 13 or 14 treatments per month. As a result, in the CY 2015 ESRD PPS final rule (79 FR 66145 through 66147), we reminded ESRD facilities and MACs that the Medicare ESRD benefit allows for the payment of 3 weekly dialysis treatments, and that additional weekly dialysis treatments may be paid only if there is documented medical justification. Additional conventional HD treatments are reimbursed at the full ESRD PPS payment if the facility's Medicare Administrative Contractor (MAC) determines the treatments are medically justified based on a patient condition, such as congestive heart failure or pregnancy. MACs have developed local coverage determinations and automated processes to pay for all the treatments reported on the claim if the ESRD facility reports diagnoses determined by the MAC to medically justify treatments beyond 3 times per week.

The option to furnish more than 3 HD treatments per week is the result of evolving technology. We believe that use of this treatment option provides a level of toxin clearance on a weekly basis similar to that achieved through 3-times weekly conventional in-center HD. However, HD treatments exceeding three times per week are generally shorter and afford patients greater flexibility in managing their ESRD and other activities. As stated above, under the ESRD PPS, we currently do not have a payment mechanism that could apply a 3 treatments-per week equivalency to claims for patients with prescriptions for more than 3 HD treatments per week that do not have medical justification (see paragraph (d) of this section). As a result, the additional payments for treatments beyond 3 per week are denied, except where medically justified. Payment for HD treatments that exceed 3 treatments per week occurs when those treatments are medically justified, as indicated by diagnosis codes. There are specific conditions that require more medical attention, documentation in the medical record, and the results of the higher frequency treatments can be objectively measured through the collection of testing data and are therefore justified as necessary. In cases where the HD exceeds 3 treatments per week for reasons other than medical justification, there is a lack of objective data to justify additional payment for HD treatments beyond 3 treatments per week.

ESRD facilities have expressed concern that due to the monthly payment limit of 13 or 14 treatments, they are unable to report all dialysis treatments on their monthly claim, and therefore, they are not appropriately paid for each treatment furnished. We understand ESRD facilities' concerns and also would like to ensure that facilities are able to accurately report all of the treatments they furnish. Therefore, we analyzed 2015 ESRD facility claims data and found that there is a discrepancy between treatments furnished and treatments billed and paid for HD patients. The data indicate that HD patients are receiving HD treatments in excess of 3 per week, but facilities are usually only being paid for 3 treatments per week. The creation of an equivalency payment mechanism serves multiple purposes. First, it allows for payment for situations in which more than 3 HD treatments are furnished in a week that complies with the 3 treatment per week payment limit. Second, it encourages facilities to report all treatments furnished. This, in turn, would provide us with the information necessary to determine exactly how many treatments are being furnished. Finally, it would allocate the total amount of payment based on 3 HD sessions per week in accordance with the number of treatments actually furnished. For these reasons, we are proposing a payment equivalency for HD treatment regimens when more than 3 treatments are furnished per week, similar to the HD-equivalency payment that has been used for PD since the composite rate payment system was implemented in 1983. As discussed in paragraph (d) of this section, while the policy would be effective January 1, 2017, we are proposing not to implement the HD equivalency payments until July 1, 2017. We believe it is necessary to delay implementation of this policy until July 1, 2017 to allow time to make operational changes to accommodate this new payment mechanism. We would expect that, for dates of service between January 1, 2017 and July 1, 2017, facilities would continue to submit claims under the current claims submission parameters. Once the operational elements are implemented on July 1, 2017, facilities will be expected to have the appropriate billing systems in place to accommodate claims submission changes. Educational materials will be distributed to stakeholders as the claims processing changes are implemented.

b. Proposed Payment Methodology for HD When More Than 3 Treatments Are Furnished per Week

For CY 2017, for adult patients, we propose to calculate a per treatment payment amount that would be based upon the number of treatments prescribed by the physician and would be composed of the ESRD PPS base rate as adjusted by applicable patient and facility-level adjustments, the home dialysis training add-on (if applicable), and the outlier payment adjustment (if applicable). As discussed above, the policy would be effective on January 1, 2017, but the operational elements would be implemented no later than July 1, 2017 to give interested parties time to operationalize the changes. For dates of service from January 1, 2017 through June 30, 2017, facilities would submit claims consistent with current payment limits. On July 1, 2017, the operational changes will be implemented and facilities would be expected to submit claims in compliance with the new policy where more than 3 HD treatments can be billed for a week and paid using the HD equivalency payment. To calculate the equivalency payment where more than 3 HD treatments are furnished per week, we would first adjust the ESRD PPS base rate by the applicable patient-level adjustments (patient age, body surface area, low body mass index, comorbidities—acute and chronic, and onset of dialysis) and facility-level adjustments (wage index, rural facility, and low-volume facility). Second, we would multiply the adjusted ESRD PPS base rate by 3 to develop the weekly treatment amount and then we would divide this number by the number of treatments prescribed to determine the per treatment amount. Third, we would multiply the calculated outlier payment amount by 3 and divide this number by the number of treatments prescribed to determine the per treatment outlier amount. Finally, we would add the per-treatment ESRD PPS base rate and the per treatment outlier amount together to determine the final per treatment payment amount. For example, a beneficiary whose prescription indicates 5 treatments per week would be paid as follows: (Adjusted Base Rate * $\frac{3}{5}$) + (Outlier Payment * $\frac{3}{5}$) = per treatment payment amount.

While we are proposing an equivalency payment based on 3 HD treatments per week, ESRD facilities submit bills monthly and, as a result, the monthly maximums presented below are the treatment limits that would be applied to 30-day and 31-day months:

Prescribed weekly treatments	Maximum number of monthly treatments—30 day month	Maximum number of monthly treatments—31 day month
4	18	19
5	23	24
6	26	27
7	30	31

For pediatric patients, the calculation would be the same as that proposed for adult patients, except that the ESRD PPS payment amount for pediatric patients would be based on the pediatric case mix adjustments and would not include the rural or low-volume facility-level adjustments.

In order to accommodate this proposed policy change, we would establish new claim processing guidelines and edits that would allow facilities to report the prescribed number of HD treatments for each patient. There would be individual claims processing system identifiers established for treatments provided 4 times per week, 5 times per week, 6 times per week, and 7 times per week. These identifiers would allow the claims processing system to adjust the payment calculation and allow the appropriate payment for each treatment.

c. Proposed Implementation Strategy

We are proposing that this policy change would be effective on January 1, 2017 but implemented on July 1, 2017, in order to allow sufficient time for CMS and ESRD facilities to implement necessary operational and systems changes. We recognize that this is a substantial change for the ESRD facility's billing systems and for the MACs and we want to allow ample time for changes to be implemented.

d. Applicability to Medically-Justified Treatments

While the majority of ESRD patients are prescribed conventional 3-times-per-week HD, we have always recognized that some patient conditions benefit from more than 3 HD sessions per week and as such, we developed a policy for payment of medically necessary dialysis treatments beyond the 3-treatments-per-week payment limit. Under this policy, the MACs determine whether additional treatments furnished during a month are medically necessary and when the MACs determine that the additional treatments are medically justified, we pay the full base rate for the additional treatments. While Medicare does not define specific patient conditions that meet the requirements of medical necessity, the MACs consider appropriate patient conditions that would result in a patient's medical need for additional dialysis treatments (for example, excess fluid). When such patient conditions are indicated on the claim, we instruct MACs to consider medical justification and the appropriateness of payment for the additional sessions.

Extra treatments that are medically justifiable would be for conditions such as congestive heart failure. The medical necessity for additional dialysis sessions must be documented in the patient's medical record at the dialysis facility and available for review upon request. The documentation should include the physician's progress notes, the dialysis records and the results of pertinent laboratory tests. The submitted medical record must support the use of the diagnosis code(s) reported on the claim and the medical record documentation must support the medical necessity of the services. This documentation would need to be available to the contractor upon request.

In section 50.A of the Medicare Benefit Policy Manual (Pub. 100–02), we explain our policy regarding payment for HD-equivalent PD and payment for more than 3 dialysis treatments per week under the ESRD PPS. This proposal does not affect our policy to pay the full ESRD PPS base rate for medically justified treatments beyond 3 treatments per week. Rather, the intent of this proposal is to provide a mechanism for payment for evolving technologies that provide for a different schedule of treatments that accommodate a patient's preference and thereby improve that patient's quality of life. In the event that a beneficiary receives traditional HD treatments in excess of 3 per week without medical justification for the additional treatments, these additional treatments will not be paid.

e. Applicability to Home and Self-Dialysis Training Treatments

Beneficiary training is crucial for the long-term efficacy of home dialysis. Under our current policy for PD training, we pay the full ESRD PPS base rate, not the daily HD-equivalent payment amount, for each PD training treatment a beneficiary receives up to the limit of 15 training treatments for PD. As we stated in the CY 2011 ESRD PPS final rule (75 FR 49056) we pay the full ESRD PPS base rate during training because it is the base rate that accounts for the costs involved in furnishing the treatment and the add-on accounts for the additional staffing costs that are incurred. As we discuss in section II.B.2, we are investigating payments and costs related to training and plan to refine training payments in the future. Until that time, we believe that paying the full base rate during training continues to support home dialysis modalities. When training accompanies HD treatments exceeding 3 per week, the training would continue to be limited to 25 sessions, in accordance with our policy for training for conventional HD.

Because the home dialysis training add-on under the ESRD PPS (described in more detail in section II.B.2 of this proposed rule) is applied to each treatment on training claims up to the applicable limits for HD or PD, we anticipate that ESRD facilities will appreciate the ability to receive payment for each training treatment when more than 3 HD treatments are furnished per week and training is furnished with each of those treatments. We believe this effect of our proposed policy would be beneficial to facilities and beneficiaries receiving HD treatment more than 3 times per week because, as mentioned above, under our current policy, our claim edits only allow payment for 13 or 14 HD treatments in a monthly billing cycle. This means that ESRD facilities can only bill for 13 or 14 treatments for the month and may not receive the full number of home dialysis training add-on for the treatments that would otherwise be billable because of these payment limits. We believe that permitting facilities to bill for training treatments that are furnished to beneficiaries receiving more than 3 HD treatments per week will allow these facilities to receive payment for training more consistently with how they are furnishing these treatments. We expect ESRD facilities to engage patients in the decision making process for determining the best candidates for additional weekly hemodialysis beyond 3 treatments per week and thoroughly discuss with the patient the potential benefits and adverse effects associated with more frequent dialysis. For example, while there could be potential quality of life and physiological benefits there is also risk of a possible increase in vascular access procedures and the potential for hypotension during dialysis.

We believe this proposed payment mechanism, if finalized, would provide several benefits. Facilities would be able to bill for treatments accurately and be paid appropriately for the treatments they furnish. This policy would provide clarity for the MACs and providers on billing and payment for HD regimens that exceed 3 treatments per week and assist MACs in determining which HD treatments should be paid at the equivalency payment rate and which HD treatments should be paid at the full base rate because the facility has provided adequate evidence of medical justification. Beneficiaries and facilities would have more flexibility to request and furnish patient-centered treatment options. Finally, the proposal would increase the accuracy of payments and data and would provide CMS the ability to monitor outcomes for beneficiaries utilizing various treatment frequencies.

2. Home and Self-Dialysis Training Add-on Payment Adjustment

a. Background

In 2014, Medicare paid approximately $30 million to ESRD facilities for home and self-dialysis training claims, $6 million of which is in the form of home dialysis training add-on payments. These payments accounted for 115,593 dialysis training treatments (77,481 peritoneal dialysis (PD) training treatments and 38,112 hemodialysis (HD) training treatments) for 12,829 PD beneficiaries and 2,443 HD beneficiaries. Hereinafter, we will refer to this training as home dialysis training. Under the ESRD PPS, there are three components to payment for home dialysis training: The base rate, a wage-adjusted home dialysis training add-on payment, and an allowable number of training treatments to which the training add-on payment can be applied.

When the ESRD PPS was implemented in 2011, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930), and therefore, the computation of the base rate included home dialysis training add-on payments made to facilities as well as all composite rate payments, which account for facility costs associated with equipment, supplies, and staffing. In response to public comments, in the CY 2011 ESRD PPS final rule, we noted that although we were continuing to include training payments in computing the ESRD PPS base rate, we agreed with commenters that we should treat training as an adjustment under the ESRD PPS. Accordingly, we finalized the home dialysis training add-on amount of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either HD or PD training or retraining (75 FR 49063). In addition, we continued the policy of paying the home dialysis training add-on payment for 15 training treatments for PD and 25 training treatments for HD. In 2011, the amount we finalized for the home dialysis training add-on was $33.44, which was updated from the previous adjustment amount of $20. This updated amount of $33.44 per treatment was based on the national average hourly wage for nurses from the Bureau of Labor Statistics data updated to 2011 (75 FR 49063), and reflects 1 hour of training time by a registered nurse (RN) for both HD and PD. Section 494.100(a)(2) of the Conditions for Coverage for ESRD Facilities stipulates that the RN must conduct the home dialysis training, but in the ESRD Program Interpretive Guidance published October 3, 2008 (*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf*) we clarify that other members of the clinical dialysis staff may assist in providing the home training. We also elaborate in this guidance that the qualified home training RN is responsible for ensuring that the training is in accordance with the requirements at § 494.100, with oversight from the ESRD facility's interdisciplinary team.

The $33.44 amount of the home dialysis training add-on was based on the national mean hourly wage for Registered Nurses as published by the Occupational Employment Statistics (OES) data compiled by the Bureau of Labor Statistics (BLS). This mean hourly wage was then inflated to 2011 by the ESRD wages and salaries proxy used in the 2008-based ESRD bundled market basket. In the calendar year (CY) 2014 ESRD PPS final rule (78 FR 72185), CMS further increased this amount from $33.44 to $50.16 to reflect 1.5 hours of training time by an RN in response to stakeholder concerns that the training add-on was insufficient. The $50.16 training add-on amount was consistent with average costs based on an analysis of pre-PPS cost report data.

In response to the CY 2016 ESRD PPS proposed rule, we received a significant number of stakeholder comments concerning the adequacy of the home dialysis training add-on for HD. Because we did not make any proposals regarding the home dialysis training add-on in the CY 2016 ESRD PPS proposed rule, we made no changes to the home dialysis training add-on for CY 2016 but we did provide a history of the home dialysis training add-on and stated our intention to conduct further analysis of the adjustment.

While some commenters, primarily patients on home HD and a manufacturer of home HD machines, requested that we increase the home dialysis training add-on payment adjustment so that more ESRD patients could receive the benefit of home HD, we also heard from large dialysis organizations (LDOs) that the current home dialysis training add-on amount is sufficient. In addition to these differing viewpoints, we received public comments indicating a wide variance in training hours per treatment and the number of training sessions provided. As we indicated in the CY 2016 ESRD PPS final rule (80 FR 69004), patients who have been trained for home HD and their caregivers have stated that the RN training time per session spanned from 2 to 6 hours per training treatment and the number of training sessions ranged from 6 to 25 sessions. Home HD patients also acknowledged that the training they received took place in a group setting, indicating perhaps that the amount of hands-on RN training time gradually decreased over the course of training so that by the end of training, the patient was able to perform home dialysis independently.

In order to incentivize the use of PD when medically appropriate, Medicare pays the same home dialysis training add-on for all home dialysis training treatments for both PD and HD, even though PD training takes fewer hours per training treatment. It has never been our intention that the training add-on payment adjustment would reimburse a facility for all of its costs associated with home dialysis training treatments. Rather, for each home dialysis training treatment, Medicare pays the ESRD PPS base rate, all applicable case-mix and facility-level adjustments, and outlier payments plus a training add-on payment of $50.16 to account for RN time devoted to training. The home dialysis training add-on payment provides ESRD facilities with payment in addition to the ESRD PPS payment amount. Therefore, the ESRD PPS payment amount plus the $50.16 training add-on payment should be considered the Medicare payment for each home dialysis training treatment and not the home dialysis training add-on payment alone.

As we indicated in the CY 2016 ESRD PPS final rule, we committed to analyzing the home dialysis training add-on to determine whether an increase in the amount of the adjustment is appropriate. To begin an analysis of the home dialysis training add-on payment adjustment, we looked at the information on 2014 ESRD facility claims and cost reports.

b. Analysis of ESRD Facility Claims Data

We analyzed the ESRD facility claims data to evaluate if the information currently reported provides a clear representation of the utilization of training. We note that after an initial home dialysis training program is completed, ESRD facilities may bill for the retraining of patients who continue to be good candidates for home dialysis. Retraining is allowed for certain reasons as specified in the Medicare Claims Processing Manual (Pub 100–4, Chapter 8, section 50.8): the patient changes from one dialysis modality to another (for example, from PD to HD); the patient's home dialysis equipment changes; the patient's dialysis setting changes; the patient's dialysis partner changes; or the patient's medical condition changes (for example, temporary memory loss due to stroke, physical impairment). Currently, we are not able to differentiate training treatments from retraining treatments. That is, all training claims are billed with condition code 73, which is what an ESRD facility would use for both training and retraining treatments. Under the current claims processing systems, there is no mechanism that limits the allowable training treatments to, 25 for HD and 15 for PD. Therefore, we are unable to clearly tell when the patient is still training on the modality versus when they have completed the initial training and need retraining for one of these reasons provided in the claims processing manual noted above. To be able to make informed decisions on future training payment policies we would need to have specificity regarding the utilization for each service. For example, once we have more specific data indicating the actual number of training treatments furnished, we could refine the payment policy. We are interested in assessing the extent to which patients are retrained and the number of retraining sessions furnished. The findings of this assessment will inform future decisions about how we compute the training add-on payment and whether we should consider payment edits for retraining treatments. For this reason, we are planning to issue sub-regulatory guidance to provide a method for facilities to report retraining treatments. We are soliciting input from stakeholders on retraining, how often retraining occurs, how much RN time is involved, and the most common reason for retraining.

In addition, ESRD facilities have indicated they are unable to report all treatments furnished on the monthly claim. For this reason, we believe the number of training treatments currently reported on claims may be inaccurate. As discussed in detail in section II.B.1.a of this proposed rule, there are claims processing edits in place that prevent reporting of HD treatments, including both training and maintenance treatments, that exceed the number of treatments typically furnished for conventional HD, that is, 3 per week, unless the additional treatments are medically justified. This is because of the longstanding Medicare payment policy of basing payment on 3 HD treatments per week, which, for claims processing purposes is 13 to 14 treatments per month. As we discuss in detail in section II.B.1.a of this proposed rule, for PD, which is furnished multiple times each day, ESRD facilities report a treatment every day of the month and MACs pay for these treatments by applying an HD-equivalent daily rate. We are proposing a similar payment approach for HD treatments furnished more than 3 times per week, which would allow facilities to report all HD treatments furnished, but payment would be made based on a 3 treatments per week daily rate. Implementation of the proposed HD payment equivalency would allow facilities to bill accurately for all the HD treatments furnished during home dialysis training, which would better align Medicare payments for training to when facilities are incurring the cost for training.

Further, we believe that finalizing the proposed HD payment equivalency and establishing coding for retraining will greatly improve the accuracy of the reporting of training treatments. We solicit comments on this approach for improving reporting on ESRD facility claims.

c. Technical Correction of the Total Training Payment in the CY 2016 Rule

In the CY 2016 Final Rule (80 FR 60093), we incorrectly cited the payment amount to facilities for HD training as $1,881 based on a total of 37.5 hours of training. The amount we should have cited is $1,254. This is the result of a multiplication error.

d. Analysis of ESRD Cost Report Data

CMS has evaluated 2014 ESRD cost report data in an effort to identify the nature of the specific costs reported by ESRD facilities associated with home dialysis training treatments. We found that there is a significant disparity among facilities with regard to their reported average cost per home dialysis training treatment particular to HD training, ranging from under $100 per treatment to as high as several thousand dollars per treatment. Because of this substantial variation, we believe that the cost report data we currently collect cannot be used to accurately gauge the adequacy of the current $50.16 amount of the per treatment training add-on and that additional cost reporting instructions are necessary. We believe that the cost difference between training treatment costs and maintenance treatment costs is primarily the additional staff time required for training and inconsistencies in how to report related costs. All other training costs, that is, equipment, supplies, and support staff are accounted for in the ESRD PPS base rate. Based on this understanding, extreme variations in staff time should not occur as the number of hours required should fluctuate only slightly for some patients depending on modality or other factors. However, one patient needing a total nursing time of 1–2 hours compared to another patient needing 50 hours for the same modality indicates a lack of precision in the data. In response to these findings and in an effort to obtain a greater understanding of costs for dialysis facilities, CMS is considering a 3-pronged approach to improve the quality and the value of the cost report data and to enable us to use the average cost per home dialysis training treatment reported by ESRD facilities to set the amount of the training add-on payment adjustment in the future.

First, CMS would complete an in-depth analysis of cost report data elements. The analysis would assist CMS in determining what areas of the cost report are being incorrectly populated by ESRD facilities, what fields are left blank, and which ESRD facilities are deviating from the instructions for the proper completion of various fields within the report. Once we identify facilities that are deviating from proper reporting procedures, we would further evaluate the specific nature of how other ESRD facilities' cost reports were completed to see if there is a systemic problem that may be the result of imprecise instructions. If so, we would update the instructions appropriately to fix the common error. If we believe the instructions are clear but facilities are not following the guidance, we would work through the MACs to correct errors. We anticipate the result of our analysis will be greater uniformity in reporting methods and in turn, heightened data quality in future years.

Second, in accordance with section 217(e) of PAMA, CMS is currently performing comprehensive audits of ESRD facility cost reports. We anticipate the audits will result in greater uniformity in reporting methods and in turn, heightened data quality in future years.

Third, we are considering an update to the independent ESRD facility cost report (CMS–265–11) to include new fields and to rework several worksheets in an effort to obtain more granularity in data on home dialysis training. Also, we are considering a locking mechanism that would prevent a facility from submitting a cost report if certain key fields have not been completed, such as those in Worksheet S, allowing CMS to capture the needed information to appropriately pay home dialysis training by an RN.

e. Proposed Increase to the Home and Self-Dialysis Training Add-on Payment Adjustment

Based on our analysis of ESRD facility claims and cost reports which we describe above, we are pursuing changes which we believe will enable us to use the data to set the home dialysis training add-on payment adjustment in the future. Although we have already begun the process to implement changes to the cost report and claims, it will take several years for the changes to be implemented and yield data we could use as the basis for a change in the home training add-on payment adjustment. However, each year since implementation of the ESRD PPS in 2011, we have received public comments about the inadequacy of the home dialysis training add-on payment adjustment. In addition, we are committed to ensuring that all beneficiaries who are appropriate candidates for home dialysis have access to these treatment options, which generally improve beneficiaries' quality of life. For these reasons, we looked for a reasonable proxy for the home training add-on so that we could provide additional payments to support home dialysis in the interim until we are able to make changes to the home dialysis training add-on based on claims and cost report data.

Under the ESRD PPS, and in accordance with section 1881(b)(14)(A)(i) of the Act, we implemented a single base rate that applies to all treatments, even though PD costs facilities less than HD in terms of staff time, equipment, and supplies. To be consistent with this payment approach for routine maintenance dialysis treatments, we implemented a single home dialysis training add-on for both PD and HD, even though home dialysis training for PD takes half the time per training treatment on average than HD.

In order to maintain this payment approach and provide an increase in the payment for home dialysis training treatments, we are proposing an increase in the single home dialysis training add-on amount for PD and HD, based on the average treatment time for PD and HD and the percentage of total training treatments for each modality as a proxy for nurse training time. We have received industry feedback that our training payment amount is not adequate. In addition, as KDOQI guidelines specify an average HD time of 4 hours and an average PD time of 2 hours, this tells us our payment should reflect a number of hours somewhere in this range. Because our current payment reflects 1.5 hours, we propose increasing the number of hours using the weighted average formula described below, until such time as we have data that concretely indicates what an adequate payment should be.

For wages, we would use the latest Occupational Employment Statistics (*http://www.bls.gov/oes/tables.htm*) released by BLS ($34.14 in 2015), inflated to CY 2017 using the wages and salaries proxy used in the 2012-based ESRD bundled market basket. This would result in a new RN hourly wage of $35.93. For the hours, we are proposing an increase to the number of hours of home dialysis training by an RN that is accounted for by the home dialysis training add-on. We would use the average treatment times for PD and HD as a proxies for training times. The sources we researched indicated 4 hours is a clinically appropriate length of time for HD and 2 hours is a clinically appropriate length of time for a PD treatment. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines and educational material from various patient advocacy groups are examples of these sources. Since PD training is approximately 67 percent of total training treatments and takes an average of 2 hours per treatment and HD is 33 percent of total training treatments and takes an average of 4 hours per treatment, we propose to base the payment for home dialysis training on 2.66 hours of treatment time ((.67 × 2 hours) + (.33 × 4 hours) = 2.66 hours) resulting in a training add-on payment of $95.57 (2.66 hours × $35.93 = $95.57). This would provide for an increase of $45.41 per training treatment (that is, $95.57 − $50.16 = $45.41). . This approach would provide a significant increase in payment for home dialysis training for CY 2017 while maintaining consistent payment for both PD and HD modalities. Again, given that we are unable at this time to utilize cost report information to set the training add-on payment and that the number of hours of home dialysis training by an RN varies over the course of training, we believe using average treatment time for PD and HD as a proxy for training by an RN is reasonable. Once we have more specific and uniform cost report data to analyze, we intend to compare the average cost per training treatment for PD and HD to the proxy value of $95.57, assess the extent to which the home dialysis training add-on reflects ESRD facility costs for home dialysis training on average, and propose a new training add-on which may either be an increase or a decrease from the CY 2017 training add-on amount.

As we did in CY 2014 when we last increased the training add-on payment, we are proposing that the proposed increase in the training add-on payment would be made in a budget neutral manner by applying a budget neutrality adjustment to the ESRD PPS base rate. The proposed increase would result in a budget neutrality adjustment of 0.999729.

3. Proposed CY 2017 ESRD PPS Update

a. ESRD Bundled Market Basket

i. Proposed CY 2017 ESRD Market Basket Update, Productivity Adjustment, and Labor-Related Share for ESRD PPS

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

Section 1881(b)(14)(F)(i)(I) of the Act, as added by section 217(b)(2)(A) of PAMA, provides that in order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the market basket percentage increase factor for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1.0 percentage point for 2018. Accordingly, for CY 2017, we will reduce the proposed amount of the market basket percentage increase factor by 1.25 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, and will further reduce it by the productivity adjustment.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRDB input price index (75 FR 49151 through 49162) and subsequently revised and rebased the ESRDB input price index in the CY 2015 ESRD final rule (79 FR 66129 through 66136). Although "market basket" technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term "ESRDB market basket," as used in this document, refers to the ESRDB input price index.

We propose to use the CY 2012-based ESRDB market basket as finalized and described in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136) to compute the CY 2017 ESRDB market basket increase factor and labor-related share based on the best available data. Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Insight (IGI), Inc.'s forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Using this methodology and the IGI forecast for the first quarter of 2016 of the CY 2012-based ESRDB market basket (with historical data through the fourth quarter of 2015), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2017 ESRDB market basket increase factor is 2.1 percent. As required by section 1881(b)(14)(F)(I)(i) of the Act as amended by section 217(b)(2) of PAMA, we must reduce the amount of the market basket increase factor by 1.25 percent, resulting in a proposed CY 2017 ESRDB market basket percentage increase factor of 0.85 percent.

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. MFP is derived by subtracting the contribution of labor and capital input growth from output growth, the detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

Using IGI's first quarter 2016 forecast, the MFP adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2017) is projected to be 0.5 percent.

For the CY 2017 ESRD payment update, we propose to continue using a labor-related share of 50.673 percent for the ESRD PPS payment, which was finalized in the CY 2015 ESRD final rule (79 FR 66136).

ii. Proposed CY 2017 ESRDB Market Basket Update, Adjusted for Multifactor Productivity (MFP)

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. For CY 2017, section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, requires the Secretary to implement a 1.25 percentage point reduction to the ESRDB market basket increase factor in addition to the productivity adjustment.

As a result of these provisions, the proposed CY 2017 ESRD market basket increase is 0.35 percent. This market basket increase is calculated by starting with the proposed CY 2017 ESRDB market basket percentage increase factor of 2.1 percent, reducing it by the mandated legislative adjustment of 1.25 percent (required by section 1881(b)(14)(F)(I)(i)), and reducing it further by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2017) of 0.5 percent. As is our general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket or MFP adjustment), we will use such data to determine the CY 2017 market basket update and MFP adjustment in the CY 2017 ESRD PPS final rule.

b. The Proposed CY 2017 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-based geographic area designations to define urban and rural areas and their corresponding wage index values. OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The latest bulletin, as well as subsequent bulletins, is available online at *http://www.whitehouse.gov/omb/bulletins_index2003-2005.*

For CY 2017, we would continue to use the same methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) for determining the wage indices for ESRD facilities. Specifically, we are updating the wage indices for CY 2017 to account for updated wage levels in areas in which ESRD facilities are located. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The proposed CY 2017 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2017 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.*

In the CY 2011 and CY 2012 ESRD PPS final rules (75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively), we also discussed and finalized the methodologies we use to calculate wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area.

We apply the wage index for Guam as established in the CY 2014 ESRD PPS final rule (78 FR 72172) (0.9611) to American Samoa and the Northern Mariana Islands. We apply the statewide urban average based on the average of all urban areas within the state (78 FR 72173) (0.8637) to Hinesville-Fort Stewart, Georgia. We note that if hospital data becomes available for these areas, we will use that data for the appropriate CBSAs instead of the proxy.

A wage index floor value has been used in lieu of the calculated wage index values below the floor in making payment for renal dialysis services under the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized that we would continue to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively. We continued to apply and to reduce the wage index floor by 0.05 in the CY 2013 ESRD PPS final rule (77 FR 67459 through 67461). Although our intention initially was to provide a wage index floor only through the 4-year transition to 100 percent implementation of the ESRD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241), in the CY 2014 ESRD PPS final rule (78 FR 72173), we continued to apply the wage index floor and continued to reduce the floor by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), we finalized the continuation of the application of the wage index floor of 0.4000 to areas with wage index values below the floor, rather than reducing the floor by 0.05. We stated in that rule that we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor. Also, in that rule a commenter provided several alternative wage indexes for Puerto Rico for the CY 2016 ESRD PPS final rule: (1) Utilize our policy for areas that do not have reliable hospital data by applying the wage index for Guam as we did in implementing the ESRD PPS in the Northern Marianas and American Samoa; (2) use the U.S. Virgin Islands as a proxy for Puerto Rico, given the geographic proximity and its "non-mainland" or "island" nature; or (3) reestablish the wage index floor in effect in 2010 when Puerto Rico became the only wage areas subject to the floor, that is, 0.65.

For the CY 2017 proposed rule, we analyzed ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and compared them to mainland facilities. Specifically, we analyzed CY 2013 claims and cost report data for 37 freestanding Puerto Rico facilities and compared it to 5,024 non-Puerto Rico freestanding facilities. We found that the freestanding facilities in Puerto Rico are bigger than facilities elsewhere in the United States. The Puerto Rico facilities produce roughly twice the number of treatments as other facilities and this larger size likely results in higher labor productivity. Finally, dialysis patients in Puerto Rico are much more likely to be non-Medicare. We discuss the findings below in detail.

Total Composite Rate Cost and Operational Efficiency: Total composite rate cost per dialysis treatment is about 15 percent lower in Puerto Rico than elsewhere. This lower total cost reflects several production process differences: (1) Puerto Rico facilities make much higher use of equipment, as reflected in achieving about 50 percent more treatments per chair and (2) Approximately 30 percent of the freestanding Puerto Rico facilities indicated some operations during a third shift in comparison to only 12 percent of all other freestanding facilities in the United States. This higher rate of a third shift, on average, improves the rates of operational efficiency as some of these facilities more fully utilize equipment and decrease associated fixed costs per treatment.

Salary, Benefits, and Administrative Salaries: Salary and benefits for direct care staff includes costs for RNs, LPNs, nurse aides (NA), technicians, licensed social workers (LSWs), and registered dieticians (RDs). Although salaries and benefit expenses per chair are somewhat higher in Puerto Rico than those in other facilities, salaries and benefits expenses for direct care staff per treatment are about 19 percent lower because of the higher use rate of chairs. Including administrative salaries (including RN nurse managers), salaries and benefits per treatment are reported to be about 27 percent lower in Puerto Rico freestanding facilities when compared to other freestanding facilities.

Full-Time Employees (FTEs) per Treatment: Total direct care FTEs per treatment in Puerto Rico are about 12 percent less than elsewhere, but the data shows that Puerto Rico facilities employ a richer mix of staffing, as reflected in more than double the RNs per treatment in Puerto Rico than elsewhere. The data suggests that RNs are substituted for technicians in Puerto Rico facilities. The calculated variable of salaries and benefits per direct care FTE are approximately 8 percent lower in Puerto Rico than elsewhere. This difference likely reflects the net of a richer mix of labor and somewhat lower wage rates per employee classification.

In addition to this analysis, we researched staffing requirements for ESRD facilities located in Puerto Rico and confirmed that under Puerto Rico law, ESRD facilities cannot hire technicians and must only hire RNs. This requirement supports the data findings above, specifically, that Puerto Rico facilities employ a richer mix of staffing, as reflected in more than double the RNs per treatment in Puerto Rico than elsewhere.

We believe that this information provides evidence that in furnishing renal dialysis services, Puerto Rico could potentially have an economic disadvantage that the rest of the country may not be experiencing. Although we have this information available, we still believe that we need to engage the industry for input on potential changes and to assist us in assessing the appropriateness of discontinuing the wage index floor. Therefore, we are proposing to continue to apply a wage index floor of 0.4000 to areas with wage index values below the floor for CY 2017 and soliciting comments on the use of a wage index floor for Puerto Rico going forward. Our review of the wage indices show that CBSAs in Puerto Rico continue to be the only areas with wage index values that would benefit from a wage index floor because they are so low. Because the wage index floor is only applicable to a small number of CBSAs, the impact to the base rate through the wage index budget neutrality factor would be insignificant. To the extent other geographical areas fall below the floor in CY 2017 or beyond, we believe they should have the benefit of the 0.4000 wage index floor as well.

For CY 2017, we are soliciting public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate course of action. We are not proposing to change the wage index floor for CBSAs in Puerto Rico, but we are requesting public comments in which stakeholders can provide useful input for consideration in future decision-making. Specifically, we are soliciting comment on the useful suggestions that were submitted in last year's final rule (80 FR 69007) and reiterated above. Along with comments we will continue to review wage index values and the appropriateness of a wage index floor in the future.

ii. Application of the Wage Index Under the ESRD PPS

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2015 ESRD PPS final rule (79 FR 66136), we finalized a new labor-related share of 50.673 percent, which was based on the 2012-based ESRDB market basket finalized in that rule, and transitioned the new labor-related share over a 2-year period. Thus, for CY 2017, the labor-related share to which a facility's wage index would be applied is 50.673 percent.

c. CY2017 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy in our regulations at 42 CFR 413.237. The policy provides the following ESRD outlier items and services are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) medical/surgical supplies, including syringes, used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (iv) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding oral-only drugs used in the treatment of ESRD.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss amount. In accordance with section 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed-dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed-dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For the CY 2017 outlier policy, we would use the existing methodology for determining outlier payments by applying outlier services payment multipliers that were developed for the CY 2016 ESRD PPS final rule (80 FR 68993–68994, 69002). We used these outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2017.

For CY 2017, we propose that the outlier services MAP amounts and fixed-dollar loss amounts would be derived from claims data from CY 2015. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we propose the outlier thresholds for CY 2017 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2015. We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and fixed-dollar loss amounts every year under the ESRD PPS. We continue to believe that since the implementation of the ESRD PPS, data for CY 2015 are reflective of relatively stable ESA use, in contrast with the relatively large initial declines in the use of both EPO and darbepoetin in the first 2 years of the ESRD PPS. In 2015, there were both decreases in the use of EPO and increases in the use of darbepoetin based on estimates of average ESA utilization per session, suggesting a relative shift towards the use of darbepoetin between 2014 and 2015.

i. CY 2017 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts

For CY 2017, we are not proposing any change to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, we will continue to update the outlier services MAP amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2015 claims. For this proposed rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using 2015 claims data. The impact of this update is shown in Table 1, which compares the outlier services MAP amounts and fixed-dollar loss amounts used for the outlier policy in CY 2016 with the updated proposed estimates for this rule. The estimates for the proposed CY 2017 outlier policy, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2017 prices for outlier services.

TABLE 1—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Final outlier policy for CY 2016 (based on 2014 data price inflated to 2016)		Column II Proposed outlier policy for CY 2017 (based on 2015 data price inflated to 2017)	
	Age <18	Age > = 18	Age <18	Age > = 18
Average outlier services MAP amount per treatment	$40.20	$53.29	$40.49	$49.28
Adjustments				
Standardization for outlier services	0.9951	0.9729	1.0061	0.9786
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$39.20	$50.81	$39.92	$47.26
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$62.19	$86.97	$67.44	$83.00
Patient months qualifying for outlier payment	5.8%	6.5%	4.5%	6.7%

As demonstrated in Table 1, the estimated fixed-dollar loss amount per treatment that determines the CY 2017 outlier threshold amount for adults (Column II; $83.00) is lower than that used for the CY 2016 outlier policy (Column I; $86.97). The lower threshold is accompanied by a decline in the adjusted average MAP for outlier services from $50.81 to $47.26. For pediatric patients, there is an increase in the fixed dollar loss amount from $62.19 to $67.44. Unlike the adult patients, there was a slight increase in the adjusted average MAP for outlier services among pediatric patients, from $39.20 to $39.92.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2017 will be 6.7 percent for adult patients and 4.5 percent for pediatric patients, based on the 2015 claims data. The pediatric outlier MAP and fixed-dollar loss amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081), in accordance with 42 CFR 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. Based on the 2015 claims, outlier payments represented approximately 0.9 percent of total payments, slightly below the 1 percent target due to small overall declines in the use of outlier services. Recalibration of the thresholds using 2015 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2017. We believe the update to the outlier MAP and fixed-dollar loss amounts for CY 2017 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy. We note that recalibration of the fixed-dollar loss amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

We note that many industry stakeholder associations and renal facilities have expressed concern that the outlier target percentage has not been achieved under the ESRD PPS and have asked that CMS eliminate the outlier policy. With regard to the suggestion that we eliminate the outlier adjustment altogether, we note that, under section 1881(b)(14)(D)(ii) of the Act, the ESRD PPS must include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management. We believe that the ESRD PPS is required to include an outlier adjustment in order to comply with section 1881(b)(14)(D)(ii) of the Act.

In addition, while we believe that the ESRD PPS base rate and other payment adjustments capture the cost for the average renal patient having certain characteristics, there may continue to be certain individual patients or certain subgroups of patients, such as patients with bacterial pneumonia or monoclonal gammopathy, which were eliminated as payment adjustments factors for CY2016, who receive more ESAs or other outlier services than the average patient. We believe that the inclusion of the 1 percent outlier policy helps to protect patient access to care by providing additional payment for patients requiring higher use of outlier services not otherwise captured in the payment adjustments made under the ESRD PPS.

We understand the industry's concern that payments under the outlier policy have not reached 1 percent of total ESRD PPS payments since the implementation of the payment system. As we explained in the CY 2015 ESRD PPS final rule (78 FR 72165), each year we simulate payments under the ESRD PPS in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1 percent outlier policy. As we stated above, based on the 2015 claims, outlier payments represented approximately 0.9 percent of total payments, slightly below the 1 percent target, which could indicate that ESRD facilities are getting better at reporting outlier services. We note that we would not increase the base rate to account for years where outlier payments were less than 1 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments.

d. Proposed Impacts to the CY 2017 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the development of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections

1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment Medicare Allowable Payment (MAP) for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and regulations at § 413.230, the ESRD PPS base rate is adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, as well as applicable outlier payments or training payments.

ii. Annual Payment Rate Update for CY 2017

We are proposing an ESRD PPS base rate for CY 2017 of $231.04. This update reflects several factors, described in more detail below.

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2017 projection for the ESRDB market basket is 2.1 percent. In CY 2017, this amount must be reduced by 1.25 percentage points as required by section 1881(b)(14)(F)(i)(I), as amended by section 217(b)(2)(A) of PAMA, which is calculated as $2.1 - 1.25 = 0.85$ percent. This amount is then reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as required by section 1881(b)(14)(F)(i)(II) of the Act. The proposed multi-factor productivity adjustment for CY 2017 is 0.5 percent, thus yielding a proposed update to the base rate of 0.35 percent for CY 2017 ($0.85 - 0.5 = 0.35$ percent). Therefore, the proposed ESRD PPS base rate for CY 2017 before application of the wage index and training budget-neutrality adjustment factors would be $231.20 ($230.39 × 1.0035 = $231.20).

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2017, we are not proposing any changes to the methodology used to calculate this factor which is described in detail in CY 2014 ESRD PPS final rule (78 FR 72174). The CY 2017 proposed wage index budget-neutrality adjustment factor is 0.999552. Therefore, the proposed ESRD PPS base rate for CY 2017 before application of the training budget-neutrality adjustment factor would be $231.10 ($231.20 × 0.999552 = $231.10).

Home and Self-Dialysis Training Add-on Budget-Neutrality Adjustment Factor: Also, as discussed in section II.B.2 of this proposed rule, we are proposing an increase in the home dialysis training add-on in a budget-neutral manner. The home dialysis training add-on budget-neutrality factor ensures that the increase in the training add-on payment adjustment does not affect aggregate Medicare payments. Therefore, we are finalizing a home dialysis training add-on payment adjustment budget-neutrality adjustment factor of 0.999729, which will be applied directly to the CY 2017 ESRD PPS base rate. This application yields a CY 2017 ESRD PPS base rate of $231.04 ($231.10 × 0.999729 = $231.04).

In summary, we are proposing a CY 2017 ESRD PPS base rate of $231.04. This amount reflects a market basket increase of 0.35 percent, the CY 2017 wage index budget-neutrality adjustment factor of 0.999552, and the home dialysis training add-on payment adjustment budget-neutrality adjustment of 0.999729.

III. Proposed Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

On June 29, 2015, the Trade Protection Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted. In the TPEA, the Congress amended the Act to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act by including coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI. In addition, section 808(b) of TPEA amended section 1834 of the Act by adding a new subsection (r). Subsection (r)(1) of section 1834 of the Act provides that in the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or a provider of services paid under such section during a year (beginning with 2017) to an individual with acute kidney injury, the amount of payment under Part B for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. Section 1834(r)(2) defines "individual with acute kidney injury" to mean an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14). In this rule, we are proposing payment and billing requirements as discussed below.

B. Proposed Payment Policy for Renal Dialysis Services Furnished to Individuals With AKI

1. Definition of "Individual with Acute Kidney Injury"

Consistent with section 1834(r)(2) of the Act, we propose to define an individual with AKI as an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14). Section 1881(b)(14) of the Act contains all of the provisions related to the ESRD PPS. We interpret the reference to section 1881(b)(14) of the Act to mean that we would pay renal dialysis facilities for renal dialysis services furnished to individuals with acute loss of kidney function when the services furnished to those individuals are not payable under section 1881(b)(14) because the individuals do not have ESRD. We propose to codify the statutory definition of individual with acute kidney injury at 42 CFR 413.371 and we solicit comments on this definition.

2. The Payment Rate for AKI Dialysis

Section 1834(r)(1) of the Act, as added by section 808(b) of TPEA, provides that the amount of payment for AKI services shall be the base rate for renal dialysis services determined for a year under section 1881(b)(14). We propose to interpret this provision to mean the ESRD PPS per treatment base rate as set forth in 42 CFR 413.220, which is updated annually by the market basket less the productivity adjustment as set forth in 42 CFR 413.196(d)(1), and adjusted by any other adjustment factor applied to the ESRD PPS base rate. This amount would be established on an annual basis through rulemaking and finalized in the CY ESRD PPS final rule. We recognize that there could be rulemaking years in which legislation or policy decisions could directly impact the ESRD PPS base rate because of changes to ESRD PPS policy that may not relate to the services furnished for

AKI dialysis. For example, for CY 2017 we are applying a training add-on budget neutrality adjustment factor to the otherwise applicable base rate. In those situations, we would still consider the ESRD PPS base rate as the payment rate for AKI dialysis. We believe that the statute was clear in that the payment rate for AKI dialysis shall be the ESRD PPS base rate determined for a year under section 1881(b)(14), which we interpret to mean the finalized ESRD PPS base rate and not to be some other determined amount. As described below, ESRD facilities will have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. For example, beneficiaries with AKI may require certain laboratory tests so that their practitioner can gauge organ function and accurately adjust the dialysis prescription that would be optimal for kidney recovery. These beneficiaries would require laboratory tests specific to their condition which would not be included in the ESRD PPS and thus, would be paid for separately. For instance, an individual with AKI might need to be tested for a biochemical indication of a urea cycle defect resulting in hyperammonemia. We propose to codify the AKI dialysis payment rate in our regulations at 42 CFR 413.372 and solicit comment on this proposal. This year's proposed ESRD PPS base rate is $231.04. Accordingly, we propose that the CY 2017 payment rate for renal dialysis services furnished by ESRD facilities for individuals with AKI will be $231.04.

3. Geographic Adjustment Factor

Section 1834(r)(1) of the Act further provides that the amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for a year under section 1881(b)(14), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II). We interpret the reference to "any applicable geographic adjustment factor applied under section (D)(iv)(II)" of such section to mean the geographic adjustment factor that is actually applied to the ESRD PPS base rate for a particular facility. Accordingly, we propose to apply the same wage index that is used under the ESRD PPS, that is, the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system that are unadjusted for occupational mix. The ESRD PPS wage index policy was finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) and codified at 42 CFR 413.231. The AKI dialysis payment rate would be adjusted for wage index for a particular facility in the same way that the ESRD PPS base rate is adjusted for wage index for that facility. Specifically, we would apply the wage index to the labor-related share of the ESRD PPS base rate that we will utilize for AKI dialysis to compute the wage-adjusted per-treatment AKI dialysis payment rate. We propose that for CY 2017, the AKI dialysis payment rate would be the CY 2017 ESRD PPS base rate (established in the CY 2017 ESRD PPS final rule), adjusted by the ESRD facility's wage index. In proposed 42 CFR 413.372(a), we refer to the ESRD PPS wage index regulation at 42 CFR 413.231 as an adjustment we will apply to the ESRD PPS base rate.

4. Other Adjustments to the AKI Payment Rate

Section 1834(r)(1) also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14). For purposes of payment for AKI dialysis, we are not proposing to adjust the AKI payment rate by any other adjustments at this time. Therefore, for at least the first year of implementation of the AKI payment rate, we are not proposing to apply any of the optional payment adjustments under subparagraph (D) of section 1881(b)(14). We propose to codify our authority to adjust the AKI payment rate by any of the adjustments under section 1881(b)(14)(D) in our regulations at 42 CFR 413.373.

5. Renal Dialysis Services Included in the AKI Payment Rate

Section 1834(r)(1) provides that the AKI payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14). We propose that drugs, biologicals, laboratory services, and supplies that are considered to be renal dialysis services under the ESRD PPS as defined in 42 CFR 413.171, would be considered to be renal dialysis services for patients with AKI. As such, no separate payment would be made for renal dialysis drugs, biologicals, laboratory services, and supplies that are included in the ESRD PPS base rate when they are furnished by an ESRD facility to an individual with AKI. We propose to codify this policy in the regulations at 42 CFR 413.374(a).

However, we recognize that the utilization of items and services for beneficiaries with AKI receiving dialysis may differ from the utilization of these same services by ESRD beneficiaries. This is because we expect that individuals with AKI will only need dialysis for a finite number of days while they recover from kidney injury, while ESRD beneficiaries require dialysis indefinitely unless they receive a kidney transplant. We recognize that the intent of dialysis for patients with AKI is curative; therefore, we are proposing that we will pay for all hemodialysis treatments furnished to beneficiaries with AKI in a week, even if the number of treatments exceeds the three times-weekly limitation we apply to HD treatments furnished to beneficiaries with ESRD.

Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in 42 CFR 413.171, but that are related to their dialysis treatment as a result of their AKI and that an ESRD facility might furnish to a beneficiary with AKI, would be separately payable. In particular, an ESRD facility could seek separate payment for drugs, biologicals, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting. Therefore, we are proposing to pay for these items and services separately when they are furnished to beneficiaries with AKI receiving dialysis in ESRD facilities. We propose to codify this policy at 42 CFR 413.374(b).

C. Applicability of ESRD PPS Policies to AKI Dialysis

1. Uncompleted Dialysis Treatment

Generally, we would pay for only one treatment per day across all settings. However, similar to the policy applied under the ESRD PPS for treatments for patients with ESRD, in the interest of fairness and in accordance with Chapter 8, section 10.2 of the Medicare Claims Processing Manual, if a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, for example, a medical emergency when the patient must be rushed to an emergency room, both the ESRD facility and the hospital would be paid. We consider this to be a rare occurrence that must be fully documented to the A/B MAC's satisfaction.

2. Home and Self-Dialysis

We do not expect that beneficiaries with AKI will receive dialysis in their homes due to the duration of treatment and the unique needs of AKI. Specifically, it is our understanding that these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and get off of dialysis. Therefore, we are proposing not to extend the home dialysis benefit to beneficiaries with AKI.

3. Vaccines and Their Administration

Section 1881(b)(14)(B) of the Act specifically excludes vaccines covered under section 1861(s)(10) of the Act from the ESRD PPS. However, ESRD facilities are identified as an entity that can bill Medicare for vaccines and their administration. Therefore, we propose to allow ESRD facilities to furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in Pub. 100–04, Chapter 18 Preventive and Screening Services, section 10.2 which is located on the CMS Web site: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf.* We solicit comment on the proposal for ESRD facilities to administer vaccines to beneficiaries with AKI.

D. Monitoring of Beneficiaries With AKI Receiving Dialysis in ESRD Facilities

Because we are aware of the unique acute medical needs of the AKI population, we plan to closely monitor utilization of dialysis and all separately billable items and services furnished to individuals with AKI by ESRD facilities. For example, stakeholders have stated that beneficiaries with AKI will require frequent labs to monitor renal function or they will be at risk for developing chronic renal failure. Another recurrent concern is the flexibility necessary in providing dialysis sessions to beneficiaries with AKI. Stakeholders have told us that these patients may need frequent dialysis, but will also require days with no dialysis to test for kidney recovery. Consequently, we will closely monitor utilization of dialysis treatments and the drugs, labs and services provided to these beneficiaries.

We have met with both physician and provider associations with regard to the care of patients with AKI. Both have expressed concerns that physician oversight will be limited for these beneficiaries, based on current operational models used by ESRD facilities. They have encouraged CMS to support close monitoring of this patient population—particularly with regard to lab values—in the interest of preventing these patients from becoming ESRD patients. A close patient-physician relationship is critical for the successful outcome of the AKI patient.

E. AKI and the ESRD Conditions for Coverage

The ESRD Conditions for Coverage (CfCs) at 42 CFR part 494 are health and safety standards that all Medicare-participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all ESRD patients receive safe and appropriate care.

We propose a technical change to 42 CFR 494.1(a), statutory basis, to incorporate the changes to ESRD facilities and treatment of AKI in the Act as enacted by section 808 of the Trade Protection Extension Act of 2015 (Pub. L. 114–27, June 29, 2015) (TPEA).

While the substance of the ESRD CfCs (comprehensively updated in 2008) does not directly address treatment of patients with AKI, we believe that the current ESRD facility requirements are sufficient to ensure that such patients are dialyzed safely. For example, infection control protocols would be the same for an ESRD patient receiving maintenance dialysis and an AKI patient. For the areas in which care and care planning may differ, such as frequency of certain patient assessments, we note that the CfCs set baseline standards and do not limit additional or more frequent services that may be necessary for AKI patients receiving temporary dialysis to restore kidney function.

Accordingly, we are not proposing changes to the CfCs specific to AKI at this time. However, we are soliciting comment from the dialysis community as to whether revisions to the CfCs might be appropriate for addressing treatment of AKI in ESRD facilities. Some of our specific questions include: Should we address AKI care directly in the ESRD CfCs? Should care planning for AKI patients be addressed differently than care planning for ESRD patients? Are there other areas, such as medical records, that might be appropriate for AKI-related revisions? We do not intend to respond to comments related to potential CfC revisions for AKI in the final rule, but will consider them in future rulemaking.

F. ESRD Facility Billing for AKI Dialysis

For payment purposes, claims for beneficiaries with AKI would be identified through a specific condition code, an AKI diagnosis, an appropriate revenue code, and an appropriate Common Procedural Terminology code. These billing requirements would serve to verify that a patient has AKI and differentiate claims for AKI from claims for patients with ESRD. ESRD facilities are expected to report all items and services furnished to individuals with AKI and include comorbidity diagnoses on their claims for monitoring purposes. We anticipate that with exceptions for separately billable items and services, most of the claims policies laid out in Chapter 8 of the Medicare Claims Processing Manual will also apply to claims for dialysis furnished to AKI beneficiaries. All billing requirements will be implemented and furnished through sub-regulatory guidance.

G. Announcement of AKI Payment Rate in Future Years

In future years, we anticipate announcing the AKI payment rate in the annual ESRD PPS rule or in a **Federal Register** notice. We will adopt through notice and comment rulemaking any changes to our methodology for payment for AKI as well as any adjustments to the AKI payment rate other than the wage index. When we are not making methodological changes or adjusting (as opposed to updating) the payment rate, however, we will announce the update to the rate rather than subjecting it to public comment every year. We are proposing to announce the annual AKI payment rate in a notice published in the **Federal Register** or, alternatively, in the annual ESRD PPS rulemaking, and provide for that announcement at proposed 42 CFR 413.375. We welcome comments on announcing the AKI payment rate in future years.

IV. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

A. Background

Section 1881(h) of the Act requires the Secretary to establish an End-stage renal disease (ESRD) quality incentive program (QIP) by (1) selecting measures; (2) establishing the performance standards that apply to the individual measures; (3) specifying a performance period with respect to a year; (4) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (5) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS). This proposed rule discusses each of these elements and our proposals for their application to the ESRD QIP.

B. Proposed Changes to the Requirements for the Payment Year (PY) 2018 ESRD QIP

1. Proposal to Correct the Small Facility Adjuster (SFA) Policy for PY 2018

In the CY 2016 ESRD PPS Final Rule, we revised the calculation of the Small Facility Adjuster (SFA) (80 FR 69039). We are proposing to correct our description of the SFA for payment year (PY) 2017 and future years. Our original proposal pegged the SFA to the national mean, such that small facilities scoring below the national mean would receive an adjustment, but small facilities scoring above the national mean would not. Several commenters supported the overall objectives of the proposed SFA modification but were concerned that too few facilities would receive an adjustment under our proposed methodology. They recommended that rather than pegging the SFA to the national mean, we peg the SFA to the benchmark, which is the 90th percentile of national facility performance on a measure, such that facilities scoring below the benchmark would receive an adjustment, but those scoring above the benchmark would not. In the process of updating the finalized policy to reflect public comment, we inadvertently neglected to update this sentence from our statement of finalized policy: "For the standardized ratio measures, such as the Standardized Readmission Ratio (SRR) and Standardized Transfusion Ratio (STrR) clinical measures, the national mean measure rate (that is, $\bar{P}$) is set to 1." (80 FR 69039). Setting the ratio measures at the national mean in the SFA equation would have been inconsistent with our desired policy position and would have been unresponsive to the commenter's point. It was also inconsistent with another part of our statement on the finalized SFA methodology and was more punitive for facilities because it did not provide an adjustment for a number of small facilities that may have been adversely affected by a small number of outlier patients. Therefore, we propose to correct the description of the SFA methodology such that, for the standardized ratio measures such as the SRR and STrR clinical measures, $\bar{P}$ is set to the benchmark, which is the 90th percentile of national facility performance.

We seek comments on this proposal.

2. Proposed Changes to the Hypercalcemia Clinical Measure

During the measure maintenance process at National Quality Forum (NQF), two substantive changes were made to the Hypercalcemia clinical measure. First, plasma was added as an acceptable substrate in addition to serum calcium. Second, the denominator definition changed such that it now includes patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. Functionally, this means that a greater number of patient-months will be included in this measure, because patient-months will not be excluded from the measure calculations solely because a facility reports no calcium data for that patient during the entire three month study period.

We are proposing to update the measure's technical specifications for PY 2018 and future years to include these two substantive changes to the Hypercalcemia clinical measure included in the ESRD QIP. These changes will positively impact data completeness in the ESRD QIP because facilities' blood tests typically use plasma calcium rather than serum calcium. Including patients with unreported calcium values in the measure calculations will encourage more complete reporting of this data. Additionally, these changes will ensure that the measure aligns with the NQF-endorsed measure and can continue to satisfy the requirements of the Protecting Access to Medicare Act (PAMA), which requires that the ESRD QIP include in its measure set measures (outcomes-based, to the extent feasible), that are specific to the conditions treated with oral-only drugs.

We seek comments on this proposal.

C. Proposed Requirements for the PY 2019 ESRD QIP

1. Proposed New Measures for the PY 2019 ESRD QIP

a. Proposed Reintroduction of the Expanded NHSN Dialysis Event Reporting Measure

We first adopted the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure for the PY 2014 ESRD QIP. For that program year, we required facilities to (1) enroll in the NHSN and complete any training required by the CDC; and (2) submit three or more consecutive months of dialysis event data to the NHSN (76 FR 70268 through 69). For PY 2015, we retained the requirement for facilities to enroll in the NHSN and complete any training required by the CDC, but expanded the reporting period to require facilities to report a full 12 months of dialysis event data (77 FR 67481 through 84). Beginning with PY 2016, we replaced the NHSN Dialysis Event Reporting Measure with the clinical version of the measure (78 FR 72204 through 07). As a result, facilities were scored for purposes of the ESRD QIP based on how many dialysis events they reported to the NHSN in accordance with the NHSN protocol. We introduced the clinical version of the measure because we believed that the measure would hold facilities accountable for monitoring and preventing infections in the ESRD population. We continue to believe it is vitally important to hold facilities accountable for their actual clinical performance on this measure.

Since we introduced the NHSN Bloodstream Infection (BSI) Clinical Measure into the ESRD QIP, some stakeholders have expressed significant concerns about two distinct types of accidental or intentional under-reporting. First, these stakeholders believe that many facilities do not consistently report monthly dialysis event data for the full 12-month performance period. Second, these stakeholders believe that even with respect to the facilities that report monthly dialysis event data, many of those facilities do not consistently report all of the dialysis events that they should be reporting. (80 FR 69048). These public comments, as well as our thorough review of data reported for the PY 2015 NHSN Dialysis Event Reporting Measure and results from the PY 2014 NHSN data validation feasibility study, suggest that as many as 60–80 percent of dialysis events are under-reported.[2] [3]

We believe that there are delicate tradeoffs associated with incentivizing facilities to both report monthly dialysis event data and to accurately report such data. On the one hand, if we incentivize facilities to report monthly dialysis event data but do not hold them accountable for their performance, we believe that facilities will be more likely to accurately report all dialysis events.

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[2] Duc B. Nguyen, et al. Completeness of Methicillin-Resistant *Staphylococcus aureus* Bloodstream Infection Reporting From Outpatient Hemodialysis Facilities to the National Healthcare Safety network, 2013. Infection Control & Hospital Epidemiology, *http://journals.cambridge.org/abstract_S0899823X15002652.*

[3] Nicola D. Thompson, Matthew Wise, Ruth Belflower, Meredith Kanago, Marion A Kainer, Chris Lovell and Priti R. Patel. Evaluation of Manual and Automated Bloodstream Infection Surveillance in Outpatient Dialysis Centers. Infection Control & Hospital Epidemiology, Available on CJO 2016 doi: 10.1017/ice.2015.336.

Complete and accurate reporting is critical to maintaining the integrity of the NHSN surveillance system, enables facilities to implement their own quality improvement initiatives, and enables the CDC to design and disseminate prevention strategies. Nevertheless, incentivizing full and accurate reporting without financial consequences for poor performance will not necessarily improve patient safety. On the other hand, if we incentivize facilities to achieve high clinical performance scores without also incentivizing them to accurately report monthly dialysis event data, we believe that facilities will be less likely to report complete and accurate monthly data, which could diminish the integrity of the NHSN surveillance system and the quality improvement efforts that it supports. Maintaining an incentive structure along these lines increases the financial consequences for not achieving high clinical scores, but jeopardizes the accuracy and completeness of the dialysis event data upon which those scores are based.

In light of these considerations, we believe that the best way to strike the proper balance between these competing interests is to propose to reintroduce the expanded NHSN Dialysis Event Reporting Measure, beginning with PY 2019, and to include both this measure and the NHSN BSI Clinical Measure in the ESRD QIP measure set.

In combination with other programmatic features described more fully below (see sections IV.C.2. and IV.C.8.), we believe this reporting measure will bolster incentives for facilities to report complete and accurate data to NHSN, while the clinical measure will preserve incentives to reduce the number of dialysis events. We believe that including both of these measures in the ESRD QIP measure set will ensure that we hold facilities accountable for the frequency with which they report data to the NHSN and will address validation concerns related to the two distinct types of under-reporting of data, described above.

, we propose that beginning with PY 2019, facilities must enroll in NHSN and complete any training required by the CDC related to reporting dialysis events via NHSN, and that they must report monthly dialysis event data on a quarterly basis to the NHSN. We also propose that each quarter's data would be due 3 months after the end of the quarter. For example, data from January 1 through March 31, 2017 would need to be submitted to NHSN by June 30, 2017; data from April 1 through June 30, 2017 would need to be submitted by September 30, 2017; data from July 1 through September 30, 2017 would need to be submitted by December 31, 2017; and data from October 1 through December 31, 2017 would need to be submitted by March 31, 2018. For further information regarding NHSN's dialysis event reporting protocols, please see *http://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf*. These requirements are the same ones that previously applied to the expanded NHSN Dialysis Event Reporting Measure when that measure was included in the ESRD QIP (77 FR 67481 through 84).

Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iii) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently NQF). Under the exception set forth in 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The proposed NHSN Dialysis Event Reporting Measure is not endorsed by the NQF, but for the reasons explained above, we believe that it is appropriate to assess facilities solely based on whether they actually report full and accurate monthly dialysis event data to the NHSN. Although we recognize that the NHSN BSI Clinical Measure is currently included in the ESRD QIP measure set and that this measure and the proposed NHSN Dialysis Event Reporting Measure would be calculated using the same set of data, the two measures assess different outcomes. We believe that including both of these measures in the ESRD QIP measure set will collectively support our efforts to ensure that facilities report, and are scored based on, complete and accurate dialysis event data.

For the reasons stated above, we propose to reintroduce the NHSN Dialysis Event Reporting Measure to the ESRD QIP beginning with PY 2019.

We seek comments on this proposal.

b. Proposal for Scoring the Proposed NHSN Dialysis Event Reporting Measure

With respect to the proposed NHSN Dialysis Event Reporting measure, we are proposing to score facilities with a CCN Open Date on or before January 1, 2017. Using the methodology described below, we propose to assign the following scores for reporting different quantities of data:

Scoring Distribution for the Proposed NHSN Dialysis Event Reporting Measure:

Number of Reporting Months:

12 months = 10 points

6–11 months = 2 points

0–5 months = 0 points

We selected these scores for the following reasons: First, due to the seasonal variability of bloodstream infection rates, we want to incentivize facilities to report the full 12 months of data and reward reporting consistency over the course of the entire performance period. We therefore propose that facilities will receive 10 points for submitting twelve months of data. We recognize, however, that from the perspective of national prevention strategies and internal quality improvement initiatives, there is still some value in collecting fewer than 12 months of data from facilities. We also need at least 6 months of data in order to calculate reliable scores on the NHSN BSI Clinical Measure. For these reasons, we propose that facilities will receive 2 points for reporting between 6 and 11 months of dialysis event data. Finally, in consultation with the CDC, we have determined that NHSN BSI Clinical Measure rates are not reliable when they are calculated using fewer than six months of data. For that reason, we propose that a facility will receive 0 points on the proposed NHSN Dialysis Event Reporting Measure if it reports fewer than six months of data.

The proposed scoring methodology for the proposed NHSN Dialysis Event Reporting Measure differs slightly from what we finalized for PY 2015. For that year of the program, facilities were awarded 0 points for reporting fewer than 6 months of data, 5 points for reporting 6 consecutive months, and 10 points for reporting all 12 months of data. We believe that it is appropriate to reduce the number of points facilities receive for reporting 6–11 months of data from 5 to 2 because by PY 2019, facilities will have had 3 more years of experience reporting data to NHSN than they had for PY 2015.

2. Proposed New Measure Topic Beginning With the PY 2019 ESRD QIP

a. Proposed NHSN BSI Measure Topic

For PY 2019 and future years of the program, we are proposing to create a new NHSN BSI Measure Topic. We propose that this measure topic consist of the following two measures:

(i) NHSN (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a Clinical Measure

(ii) NHSN Dialysis Event Reporting Measure.

We believe it is appropriate to combine these two measures into one measure topic, because data from the reporting measure will be used to score both that measure and the clinical measure, and combining both measures under the same measure topic will better enable us to precisely calibrate incentives for complete and accurate reporting and high clinical performance. The NHSN BSI Clinical Measure and the NHSN Dialysis Event Reporting Measure are mutually reinforcing because one measure encourages accurate reporting while the other uses the reported data to assess facility performance on preventing BSIs in their patients. Therefore, combining the reporting and clinical measures under the same measure topic will simplify the process of weighting each of the two measures, such that incentives from one measure can be simply reallocated to the other if new evidence suggests that the incentives are not properly balanced to optimize both reporting and prevention.

We seek comments on this proposal.

3. Proposal To Establish a New Safety Measure Domain

We currently use two domains in the ESRD QIP for purposes of scoring. The first of these domains, termed the Clinical Measure Domain, is defined as an aggregated metric of facility performance on the clinical measures and measure topics in the ESRD QIP, and we use subdomains within the Clinical Measure Domain for the purposes of calculating the Clinical Measure Domain score (79 FR 66213). We also have a Reporting Measure Domain, in which scores on reporting measures are weighted equally (79 FR 66218 through 66219).

In section IV.C.2 above, we describe the proposed NHSN BSI Measure Topic. We believe that this measure topic, consisting of both the proposed NHSN Dialysis Event Reporting Measure and the NHSN BSI Clinical Measure, is fundamentally different from the other measures and measure topics included in the ESRD QIP's measure set. The two measures included in this measure topic are inextricably linked because data from the reporting measure is used to calculate the clinical measure. No other reporting measures currently included in the ESRD QIP's measure set are used for this purpose. As mentioned above, placing these two measures together in a single measure topic that is given a single measure topic score, creates the important linkage between the two measures and balances out the competing incentives involved: Incentivizing complete and accurate reporting of data to NHSN while also incentivizing facilities to achieve high clinical scores on the clinical measure. Without complete and accurate data, the clinical measure will not produce meaningful results. The measure topic is also different from others included in the ESRD QIP's measure set because it is comprised of both a clinical measure and a reporting measure. It therefore does not appropriately belong in either the Reporting Measure Domain or the Clinical Measure Domain.

Because of these fundamental differences, we propose to remove the Safety Subdomain from the Clinical Measure Domain for PY 2019 and future payment years. We propose that the Safety Subdomain will instead be a new, third Domain, separate from and in addition to the existing Clinical and Reporting Measure Domains. Additionally, we propose that facilities will receive a Safety Measure Domain score in addition to their Reporting Measure Domain and Clinical Measure Domain scores. We describe our proposed scoring methodology more fully below in section IV.C.6, but we propose that these three Domain scores will be combined and weighted to produce a Total Performance Score (TPS) for each facility.

We seek comments on these proposals.

4. Proposal for Scoring the Proposed NHSN BSI Measure Topic

In light of the concerns we have discussed above, including the accidental or intentional underreporting of dialysis event data, we are proposing to assign significant weight to the proposed NHSN Dialysis Event Reporting Measure in the overall NHSN BSI Measure Topic score. However, our proposed weighting scheme also reflects our goal to incentivize strong performance on the clinical measure. For these reasons, we propose that the NHSN Dialysis Event Reporting Measure be weighted at 40 percent of the measure topic score and the NHSN BSI Clinical Measure be weighted at 60 percent of the measure topic score. The formula below depicts how the NHSN BSI Measure Topic would be scored.

Proposed Formula To Derive NHSN BSI Measure Topic Score:

[NHSN Dialysis Event Reporting Measure Score * 0.4] + [NHSN BSI Clinical Measure Score * 0.6] = Measure Topic Score

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We seek comment on this proposal.

5. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2019 ESRD QIP

In the calendar year (CY) 2016 ESRD PPS final rule, we finalized that for PY 2019, the performance standards, achievement thresholds, and benchmarks for the clinical measures would be set at the 50th, 15th and 90th percentile, respectively, of national performance in CY 2015, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2019 program prior to the beginning of the performance period. (80 FR 69060). At this time, we do not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2015. Nevertheless, we are able to estimate these numerical values based on the most recent data available. For the Vascular Access Type, Hypercalcemia, NHSN BSI and ICH CAHPS clinical measures, this data comes from the period of January through December 2015. For the SRR and STrR clinical measures, this data comes from the period of January through December 2014. In Table 2, we have provided the estimated numerical values for all of the finalized PY 2019 ESRD QIP clinical measures. We will publish updated values for the clinical measures, using data from the first part of CY 2016, in the CY 2017 ESRD PPS final rule.

TABLE 2—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2019 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type			
%Fistula	53.72%	79.62%	66.04%
%Catheter	17.06%	2.89%	9.15%
Hypercalcemia	4.21%	0.32	1.85%
NHSN Bloodstream Infection SIR	1.812	0	0.861
Standardized Readmission Ratio	1.276	0.629	0.998
Standardized Transfusion Ratio	1.470	0.431	0.923
Comprehensive Dialysis Adequacy Measure Set	86.85%	97.19%	92.53%
ICH CAHPS: Nephrologists' Communication and Caring	56.41%	77.06%	65.89%
ICH CAHPS: Quality of Dialysis Center Care and Operations	52.88%	71.21%	60.75%
ICH CAHPS: Providing Information to Patients	72.09%	85.55%	78.59%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.84%	77.42%	62.26%
ICH CAHPS: Overall Rating of the Dialysis Facility	51.18%	80.58%	65.13%

In previous rulemaking, we have finalized policies to the effect that if final numerical values for the performance standard, achievement threshold, and/or benchmark were worse than they were for that measure in the previous year of the ESRD QIP, then we would substitute the previous year's performance standard, achievement threshold, and/or benchmark for that measure. We finalized this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years. In light of recent discussions with CDC, we have determined that in certain cases it may be appropriate to re-baseline the NHSN BSI Clinical Measure, such that expected infection rates are calculated on the basis of a more recent year's data. In such cases, numerical values assigned to performance standards may appear to decline, even though they represent higher standards for infection prevention. For this reason, with the exception of the NHSN BSI Clinical Measure, we propose to substitute the PY 2018 performance standard, achievement threshold, and/or benchmark for any measure that has a final numerical value for a performance standard, achievement threshold, and/or benchmark that is worse than it was for that measure in the PY 2018 ESRD QIP. We also propose that the performance standards for the NHSN BSI Clinical Measure for PY 2019 will be used irrespective of what values were assigned to the performance standards for PY 2018.

We seek comments on this proposal.

6. Proposal for Weighting the Proposed Safety Measure Domain Within the TPS and Proposal To Change the Weighting of the Clinical Measure Domain for PY 2019

As discussed in Section IV.C.3 above, we are proposing to remove the Safety Subdomain from the Clinical Measure Domain and establish it as a third domain alongside the Clinical Measure and Reporting Measure Domains for the purposes of scoring facilities and determining Total Performance Scores.

In light of stakeholder comments we have received about the prevalence of under-reporting for the NHSN BSI Clinical Measure, as well as the tradeoffs (discussed more fully in section IV.C.1.a. above) between our desire to maintain strong incentives for facilities to report bloodstream infections and to prevent those infections, and because the Safety Domain is comprised of a single measure topic, we believe it is necessary to reduce the weight of the Safety Measure Domain as a percentage of the TPS. However, we believe it is important to maintain as much consistency as possible in the ESRD QIP scoring methodology. Therefore, we are proposing to gradually reduce the weight of the Safety Measure Domain to 15 percent of the TPS in PY 2019, and then reduce it further in PY 2020, as proposed below. We further propose that the Clinical Measure Domain will be weighted at 75 percent of the TPS, and the Reporting Measure Domain will continue to be weighted at 10 percent of the TPS because we do not want to diminish the incentives to report data on the reporting measures.

In the CY 2015 ESRD PPS final rule, we finalized the criteria we will use to assign weights to measures in a facility's Clinical Measure Domain score (79 FR 66214 through 66216). Under these criteria, we take into consideration: (1) the number of measures and measure topics in a subdomain; (2) how much experience facilities have had with the measures; and (3) how well the measures align with CMS' highest priorities for quality improvement for patients with ESRD.

With respect to criterion 3, one of our top priorities for improving the quality of care furnished to ESRD patients includes increasing the number and significance of both outcome and patient experience of care measures because these measures track important patient outcomes, instead of focusing on the implementation and achievement of clinical processes that may not result in improved health for patients.[4] We believe that a shift toward outcome measures will establish a sounder connection between payment and clinical results that matter to patients. We similarly believe that it is important to prioritize measures of patient experience because high performance on these measures improves clinical outcomes and patient retention. Accordingly, we believe that increasing the impact of outcome and patient experience of care measures in the ESRD QIP measure set will ensure that facilities that fail to perform well on these measures are much more likely to receive a payment reduction.

In light of the proposed addition of the Safety Measure Domain as well as the policy priorities discussed above, we are proposing to change the Clinical Measure Domain weighting for the PY 2019 ESRD QIP. Specifically, we are proposing to increase the weight of the

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[4] CMS Quality Strategy, page 10, 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

Vascular Access Type, Dialysis Adequacy and Hypercalcemia measures by 1 percentage point each in the Clinical Measure Domain. This will result in a minor reduction of the weight that each of these measures receives as a percentage of the TPS, which is consistent with our policy to assign greater weight to outcome and experience of care measures. We are also proposing to apportion six percent of the Clinical Measure Domain to the SRR and ICH CAHPS measures, and to apportion the remaining five percent to the STrR measure. We believe this is appropriate because it distributes points as equally as possible among the outcome and experience of care measures, with a slight preference for SRR and ICH CAHPS because facilities will have had more experience with these measures than they will have had with STrR.

For the reasons discussed above, we propose to use the following weighting system in Table 3 below, for calculating a facility's Clinical Measure Domain score for PY 2019. For comparison, in Table 4, we have also provided the Measure Weights we originally finalized for PY 2019 in the CY 2016 ESRD PPS Final Rule (80 FR 69063).

TABLE 3—PROPOSED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2019 ESRD QIP

Measures/Measure topics by subdomain	Measure weight in the clinical measure domain score (proposed for PY 2019)	Measure weight as percent of TPS (proposed for PY 2019)
Patient and Family Engagement/Care Coordination Subdomain	42%	
ICH CAHPS measure	*26%*	*19.5%*
SRR measure	*16%*	*12%*
Clinical Care Subdomain	58%	
STrR measure	12%	*9%*
Dialysis Adequacy measure	19%	*14.25%*
Vascular Access Type measure topic	19%	*14.25%*
Hypercalcemia measure	8%	*6%*

Note: For PY 2019, we are proposing that the Clinical Domain will make up 75% of a facility's Total Performance Score (TPS). The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

TABLE 4—FINALIZED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2019 ESRD QIP (FINALIZED IN THE CY 2016 ESRD PPS FINAL RULE)

Measures/Measure topics by subdomain	Measure weight in the clinical measure domain score (finalized for PY 2019)	Measure weight as percent of TPS (finalized for PY 2019)
Safety Subdomain	20%	
NHSN BSI Clinical Measure	20%	18%
Patient and Family Engagement/Care Coordination Subdomain	30%	
ICH CAHPS measure	20%	18%
SRR measure	10%	9%
Clinical Care Subdomain	50%	
STrR measure	7%	6.3%
Dialysis Adequacy measure	18%	16.2%
Vascular Access Type measure topic	18%	16.2%
Hypercalcemia measure	7%	6.3%

In the CY 2016 ESRD PPS Final Rule, we finalized a requirement that, to be eligible to receive a TPS, a facility had to be eligible for at least one reporting measure and at least one clinical measure (80 FR 69064). With the proposed addition of the Safety Measure Domain for PY 2019, we are proposing a change to this policy. Specifically, for PY 2019, we propose that to be eligible to receive a TPS, a facility must be eligible for at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Measure Domain. As such, facilities do not need to receive a score on a measure in the Safety Measure Domain in order to be eligible to receive a TPS. The NHSN BSI Clinical Measure and the NHSN Dialysis Event Reporting Measure have the same eligibility requirements (specifically they require that a facility treated at least 11 eligible patients during the performance period). We are proposing this change in policy to avoid a situation in which a facility is eligible to receive a TPS when they only receive a score for a single measure topic. We are not proposing any changes to the policy that a facility's TPS will be rounded to the nearest integer, with half of an integer being rounded up.

We seek comments on these proposals.

7. Example of the Proposed PY 2019 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the proposed scoring methodology for PY 2019. Figures 1 through 4 illustrate how to calculate the Clinical Measure Domain score, the Reporting Measure Domain score, the Safety Measure Domain score, and the TPS. Figure 5 illustrates the full proposed scoring methodology for PY 2019. Note that for this example, Facility A, a hypothetical facility, has performed very well.

Figure 1 illustrates the methodology used to calculate the Clinical Measure Domain score for Facility A.

FIGURE 1:

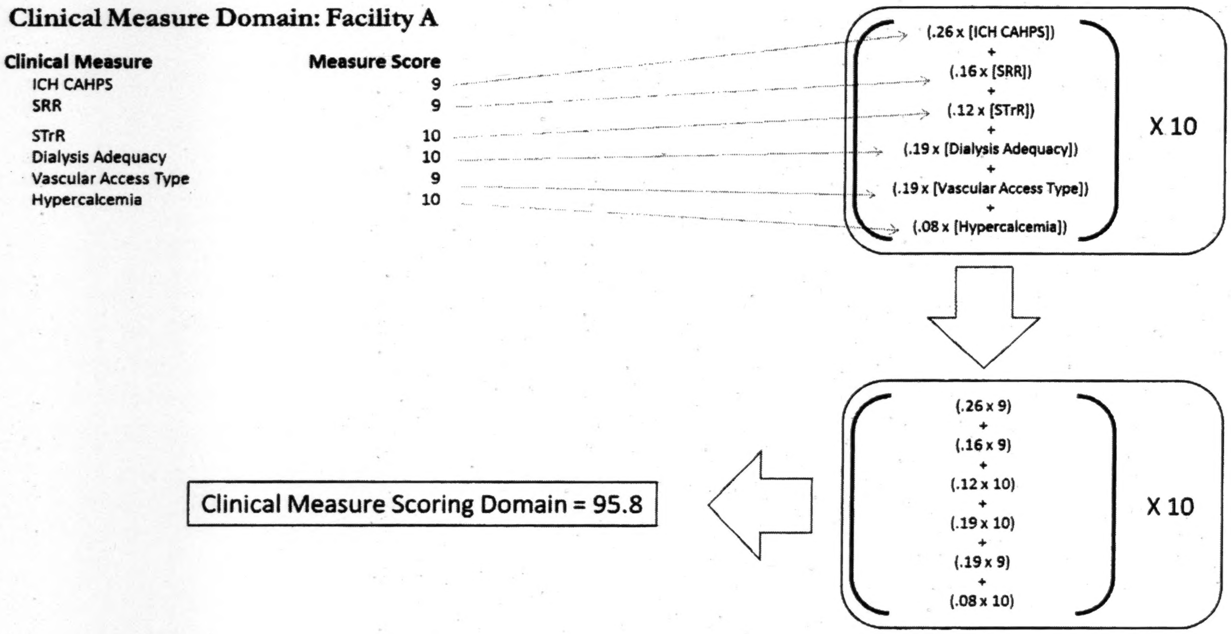
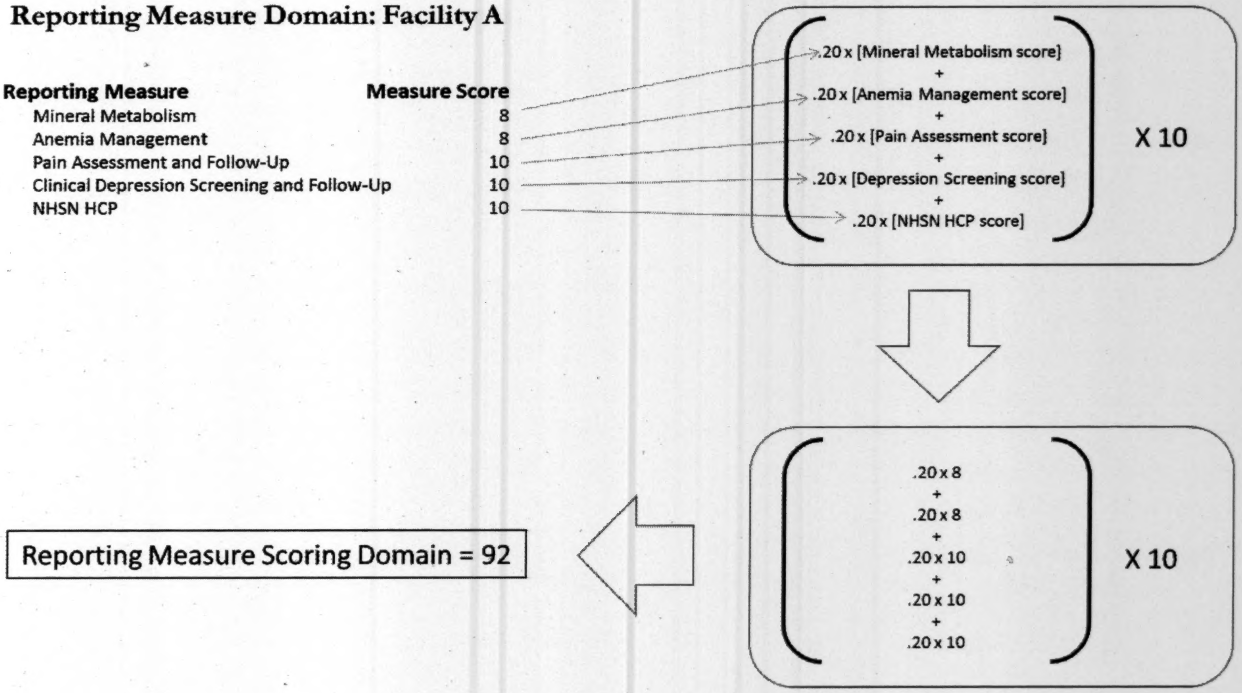

Clinical Measure Domain: Facility A
Clinical Measure
Measure Score
ICH CAHPS 9
SRR 9
STrR 10
Dialysis Adequacy 10
Vascular Access Type 9
Hypercalcemia 10
(.26 x [ICH CAHPS])
+
(.16 x [SRR])
+
(.12 x [STrR])
+
(.19 x [Dialysis Adequacy])
+
(.19 x [Vascular Access Type])
+
(.08 x [Hypercalcemia])
X 10
(.26 x 9)
+
(.16 x 9)
+
(.12 x 10)
+
(.19 x 10)
+
(.19 x 9)
+
(.08 x 10)
X 10
Clinical Measure Scoring Domain = 95.8

Figure 2 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 2:



Reporting Measure Domain: Facility A

Reporting Measure	Measure Score
Mineral Metabolism	8
Anemia Management	8
Pain Assessment and Follow-Up	10
Clinical Depression Screening and Follow-Up	10
NHSN HCP	10

.20 x [Mineral Metabolism score]
+
.20 x [Anemia Management score]
+
.20 x [Pain Assessment score]
+
.20 x [Depression Screening score]
+
.20 x [NHSN HCP score]
X 10
.20 x 8
+
.20 x 8
+
.20 x 10
+
.20 x 10
+
.20 x 10
X 10

Reporting Measure Scoring Domain = 92

Figure 3 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 3:

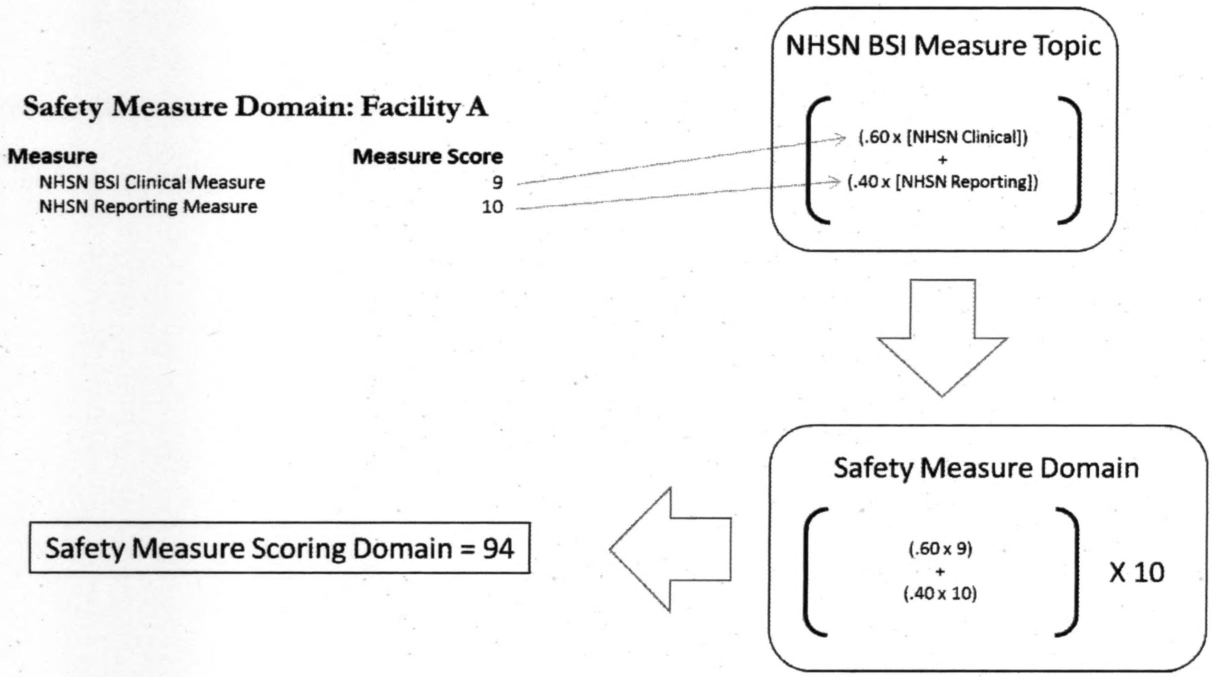
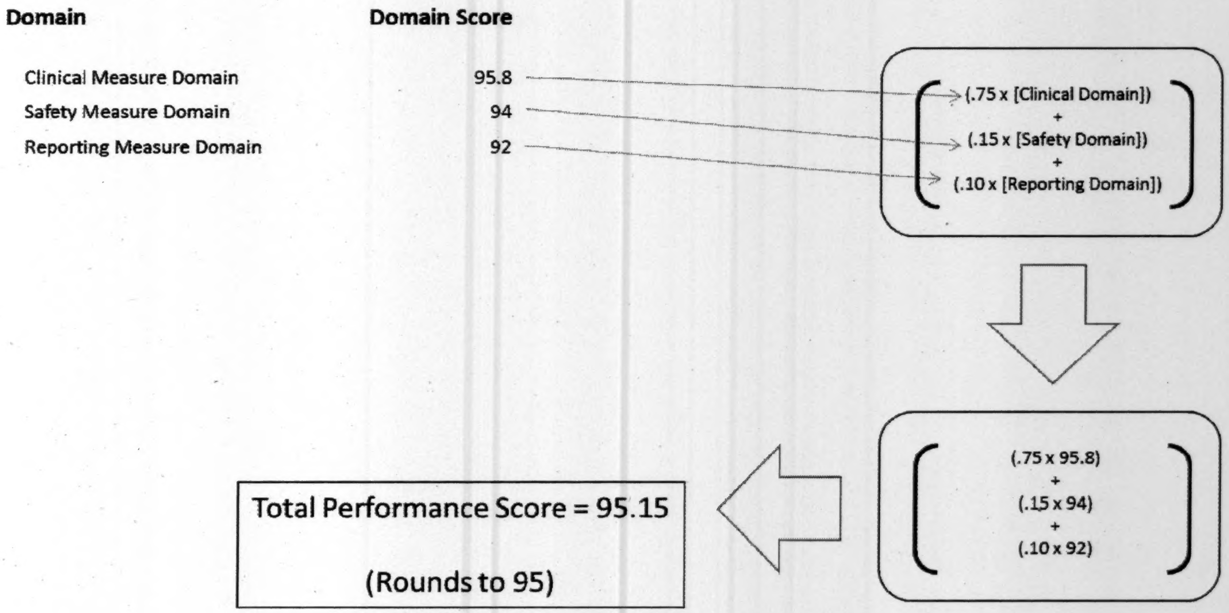

Safety Measure Domain: Facility A
Measure
Measure Score
NHSN BSI Clinical Measure
9
NHSN Reporting Measure
10
NHSN BSI Measure Topic
(.60 x [NHSN Clinical])
+
(.40 x [NHSN Reporting])
Safety Measure Domain
(.60 x 9)
+
(.40 x 10)
X 10
Safety Measure Scoring Domain = 94

Figure 4 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 4:

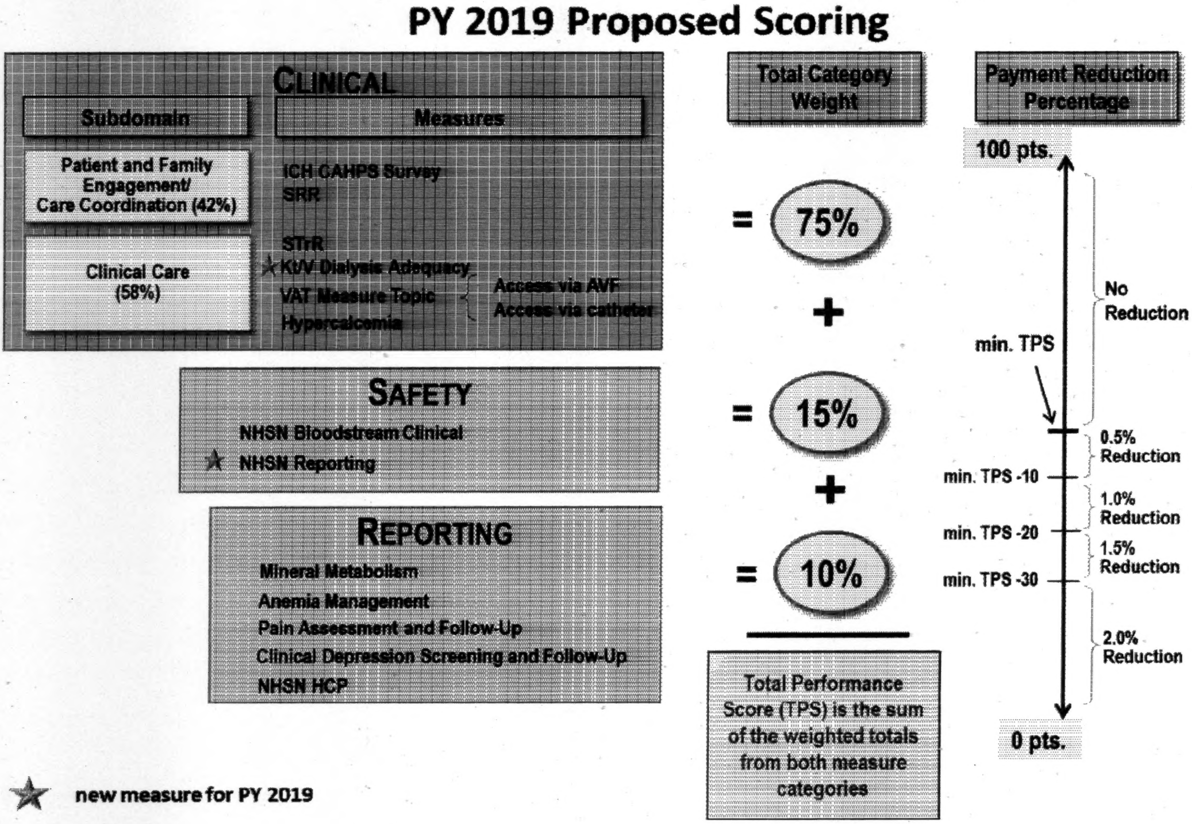


Total Performance Score: Facility A

Domain
Domain Score
Clinical Measure Domain
95.8
Safety Measure Domain
94
Reporting Measure Domain
92
(.75 x [Clinical Domain])
+
(.15 x [Safety Domain])
+
(.10 x [Reporting Domain])
(.75 x 95.8)
+
(.15 x 94)
+
(.10 x 92)
Total Performance Score = 95.15
(Rounds to 95)

Figure 5 illustrates the full scoring methodology for PY 2019.

FIGURE 5:


PY 2019 Proposed Scoring
CLINICAL
Subdomain
Measures
Patient and Family Engagement/ Care Coordination (42%)
ICH CAHPS Survey
SRR
Clinical Care (58%)
STrR
Kt/V Dialysis Adequacy
VAT Measure Topic
Access via AVF
Access via catheter
Hypercalcemia
SAFETY
NHSN Bloodstream Clinical
NHSN Reporting
REPORTING
Mineral Metabolism
Anemia Management
Pain Assessment and Follow-Up
Clinical Depression Screening and Follow-Up
NHSN HCP
Total Category Weight
= 75%
+
= 15%
+
= 10%
Total Performance Score (TPS) is the sum of the weighted totals from both measure categories
Payment Reduction Percentage
100 pts.
No Reduction
min. TPS
0.5% Reduction
min. TPS -10
1.0% Reduction
min. TPS -20
1.5% Reduction
min. TPS -30
2.0% Reduction
0 pts.
new measure for PY 2019

8. Proposed Payment Reductions for the PY 2019 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the ESRD QIP scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2016 ESRD PPS final rule, we finalized our proposal for calculating the minimum TPS for PY 2019 and future payment years (80 FR 69067). Under our current policy, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) It performs at the performance standard for each clinical measure; and (ii) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2017 reporting measures (80 FR 69067).

We were unable to calculate a minimum TPS for PY 2019 in the CY 2016 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated that we would publish the minimum TPS for the PY 2019 ESRD QIP in the CY 2017 ESRD PPS final rule (80 FR 69068).

Based on the estimated performance standards listed above, we estimate that a facility must meet or exceed a minimum TPS of 59 for PY 2019. For all of the clinical measures except the SRR and STrR, these data come from CY 2015. The data for the SRR and STrR clinical measures come from CY 2014 Medicare claims. For the ICH CAHPS clinical measure, we set the performance standard to zero for the purposes of determining this minimum TPS, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2019 performance period. We are proposing that a facility failing to meet the minimum TPS, as established in the CY 2017 ESRD PPS final rule, will receive a payment reduction based on the estimated TPS ranges indicated in Table 5 below.

TABLE 5—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2019 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction
100—59	0.0%
58—49	0.5%
48—39	1.0%
38—29	1.5%
28—0	2.0%

We seek comments on these proposals.

9. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data validation program in CY 2013 for the ESRD QIP, and procured the services of a data validation contractor that was tasked with validating a national sample of facilities' records as reported to Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). For validation of CY 2014 data, our first priority was to develop a methodology for validating data submitted to CROWNWeb under the pilot data validation program. That methodology was fully developed and adopted through the rulemaking process. For the PY 2016 ESRD QIP (78 FR 72223 through 72224), we finalized a requirement to sample approximately 10 records from 300 randomly selected facilities; these facilities had 60 days to comply once they received requests for records. We continued this pilot for the PY 2017 and PY 2018 ESRD QIP, and propose to continue doing so for the PY 2019 ESRD QIP. Under this continued validation study, we will sample the same number of records (approximately 10 per facility) from the same number of facilities (that is, 300) during CY 2017. If a facility is randomly selected to participate in the pilot validation study but does not provide us with the requisite medical records within 60 calendar days of receiving a request, then we propose to deduct 10 points from the facility's TPS. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

In the CY 2015 ESRD PPS final rule, we also finalized that there will be a feasibility study for validating data reported to the Centers for Disease Control and Prevention (CDC's) National Healthcare Safety Network (NHSN) Dialysis Event Module for the NHSN BSI Clinical Measure. Healthcare-Acquired Infections (HAI) are relatively rare, and we finalized that the feasibility study would target records with a higher probability of including a dialysis event, because this would enrich the validation sample while reducing the burden on facilities. This methodology resembles the methodology we use in the Hospital Inpatient Quality Reporting Program to validate the central line-associated bloodstream infection measure, the catheter-associated urinary tract infection measure, and the surgical site infection measure (77 FR 53539 through 53553).

For the PY 2019 ESRD QIP, we propose to randomly select 35 facilities to participate in an NHSN dialysis event validation study by submitting 10 patient records covering two quarters of data reported in CY 2017. A CMS contractor will send these facilities requests for medical records for all patients with "candidate events" during the evaluation period; *i.e.*, patients who had any positive blood cultures; received any intravenous antimicrobials; had any pus, redness, or increased swelling at a vascular access site; and/or were admitted to a hospital during the evaluation period. Facilities will have 30 calendar days to respond to the request for medical records based on candidate events either electronically or on paper. If the contractor determines that additional medical records are needed to reach the 10-record threshold from a facility to validate whether the facility accurately reported the dialysis events, then the contractor will send a request for additional, randomly selected patient records from the facility. The facility will have 30 calendar days from the date of the letter to respond to the request. With input from CDC, the CMS contractor will utilize a methodology for reviewing and validating records from candidate events and randomly selected patients, in order to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. If a facility is selected to participate in the validation study but does not provide CMS with the requisite lists of positive blood cultures within 30 calendar days of receiving a request, then we propose to deduct 10 points from the facility's TPS. Information from the validation study may be used in future years of the program to inform our consideration of future policies that would incorporate NHSN data accuracy into the scoring process.

We recognize that facilities have previously had 60 days to respond to these requests. However, in the process of implementing the pilot validation study for CY 2015 data, we recognized that the validation contractor did not have enough time to initiate requests, receive responses, validate data reported to NHSN, and generate a comprehensive validation report before the end of the contract cycle. Although facilities will have less time, the 30-day response requirement is consistent with validation studies conducted in the Hospital IQR Program, and we believe that 30 days is a reasonable amount of time for facilities to obtain and transmit the requisite medical records.

We seek comments on this proposal.

D. Proposed Requirements for the PY 2020 ESRD QIP

1. Proposed Replacement of the Mineral Metabolism Reporting Measure Beginning with the PY 2020 Program Year

We consider a quality measure for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (in other words, the measure is topped-out); (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY 2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and also adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure would address the unique needs of a specific subset of the ESRD population (79 FR 66174).

Subsequent to the publication of the CY 2016 ESRD PPS final rule, we evaluated the finalized PY 2019 ESRD QIP measures that would be continued in PY 2020 against all of these criteria. We determined that none of these measures met criterion (1), (2), (3), (4), (5) or (6). As part of this evaluation for criterion one, we performed a statistical analysis of the PY 2019 measures to determine whether any measures were "topped out." The full results of this analysis can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html* and a summary of our topped-out analysis results appears in Table 6 below.

TABLE 6—PY 2020 CLINICAL MEASURES INCLUDING FACILITIES WITH AT LEAST 11 ELIGIBLE PATIENTS PER MEASURE

Measure	N	75th/25th Percentile	90th/10th Percentile	Std Error	Statistically indistinguishable	Truncated Mean	Truncated SD	TCV	TCV's 0.10
Kt/V Delivered Dose above minimum	6210	96.0	98.0	0.093	No	92.5	4.20	0.05	Yes
Fistula Use	5906	73.2	79.6	0.148	No	65.7	8.88	0.14	No
Catheter Use	5921	5.43	2.89	0.093	No	90.1[1]	5.16	<0.01	Yes
Serum Calcium >10.2	6257	0.91	0.32	0.049	No	97.8[1]	1.48	<0.01	Yes
NHSN—SIR	5781	0.41	0.00	0.011	No	0.963	0.57	<0.01	Yes
SRR	5739	0.82	0.64	0.004	No	0.995	0.21	<0.01	Yes
STrR	5650	0.64	0.43	0.008	No	0.965	0.37	<0.01	Yes
SHR	6086	0.79	0.63	0.004	No	0.983	0.23	<0.01	Yes
ICH CAHPS.									
Nephrologists communication and caring	3349	71.8	77.1	0.159	No	65.7	7.11	0.11	No
Quality of dialysis center care and operations	3349	66.2	71.2	0.134	No	60.9	6.20	0.10	No
Providing information to patients	3349	82.4	85.6	0.101	No	78.4	4.61	0.06	Yes
Rating of Nephrologist	3349	69.9	76.6	0.204	No	62.0	9.29	0.15	No
Rating of dialysis facility staff	3349	70.9	77.4	0.215	No	62.0	9.92	0.16	No
Rating of dialysis center	3349	73.8	80.6	0.221	No	64.8	10.18	0.16	No

(1) Truncated mean for percentage is reversed (100%—truncated mean) for measures where lower score = better performance.

As the information in Table 6 indicates, none of these clinical measures are currently topped-out in the ESRD QIP. Accordingly, we are not proposing to remove any of these measures from the ESRD QIP for PY 2020 because they are topped out.

We consider the data sources we use to calculate our measures based on the reliability of the data, and we also try to use CROWNWeb data whenever possible. The Mineral Metabolism measure currently in the ESRD QIP measure set uses CROWNWeb data to determine how frequently facilities report serum phosphorus data, but it also uses Medicare claims data to exclude patients when they were treated at a facility fewer than seven times in a month. There is no evidence to suggest that the Mineral Metabolism reporting measure is leading to negative or unintended clinical consequences. However, we do not think it is optimal to use claims data to calculate the measure because that is inconsistent with our intention to increasingly use CROWNWeb as the data source for calculating measures in the ESRD QIP. There is also another available measure that can be calculated using only CROWNWeb data and that we believe is as reliable as the Mineral Metabolism Reporting Measure. The measure also excludes patients using criteria consistent with that used by other ESRD QIP measures. For these reasons, we are proposing to remove the Mineral Metabolism Reporting Measure from the ESRD QIP measure set beginning with the PY 2020 program and to replace that measure with the proposed Serum Phosphorus Reporting measure, the specifications for which are described below in section IV.D.2.c.i.

We seek comments on this proposal.

2. Proposed Measures for the PY 2020 ESRD QIP

a. PY 2019 Measures Continuing for PY 2020 and Future Payment Years

We previously finalized 12 measures in the CY 2016 ESRD PPS final rule for the PY 2019 ESRD QIP, and these measures are summarized in Table 7 below. In accordance with our policy to continue using measures unless we propose to remove or replace them, (77 FR 67477), we will continue to use 11 of these measures in the PY 2020 ESRD QIP. As noted above, we are proposing to replace the Mineral Metabolism

Reporting Measure with the Serum Phosphorus Reporting Measure and we are proposing to reintroduce the NHSN Dialysis Event Reporting Measure into the ESRD QIP measure set beginning with PY 2019.

TABLE 7—PY 2019 ESRD QIP MEASURES BEING CONTINUED IN PY 2020

NQF #	Measure title and description
0257	Vascular Access Type: AV Fistula, a clinical measure. Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter ≥ 90 days, a clinical measure. Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
1454	Hypercalcemia, a clinical measure. Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
N/A	Standardized Readmission Ratio, a clinical measure. Standardized hospital readmissions ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned readmissions.
N/A	Standardized Transfusion Ratio, a clinical measure. Risk-adjusted standardized transfusion ratio for all adult Medicare dialysis patients. Number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. Facility administers, using a third-party CMS-approved vendor, the ICH CAHPS survey twice in accordance with survey specifications and submits survey results to CMS.
N/A	Anemia Management Reporting, a reporting measure. Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.
N/A	Pain Assessment and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.
N/A	Clinical Depression Screening and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before February 1 of the year following the performance period.
N/A	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to CDC's NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15 of the performance period.
N/A	Kt/V Dialysis Adequacy Comprehensive Clinical Measure. Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
NA	NHSN Dialysis Event Reporting Measure (Proposed for PY 2019 in Section IV.C.1.a. of this Proposed Rule).

b. Proposed New Clinical Measures Beginning With the PY 2020 ESRD QIP

i. Proposed Standardized Hospitalization Ratio (SHR) Clinical Measure

Background

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year.[5] Hospitalizations account for approximately 40 percent of total Medicare expenditures for ESRD patients.[6] Measures of the frequency of hospitalization have the potential to help control escalating medical costs, play an important role in identifying potential problems, and help facilities provide cost-effective health care.

At the end of 2013 there were 661,648 patients being dialyzed, of which 117,162 were new (incident) ESRD patients.[7] In 2013, total Medicare costs for the ESRD program were $30.9 billion, a 1.6 percent increase from 2012.[8] Correspondingly, hospitalization costs for ESRD patients are very high with Medicare costs of over $10.3 billion in 2013.

Hospitalization measures have been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 1995. The Dialysis Facility Reports are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance. In particular, the Standardized Hospitalization Ratio (SHR) for Admissions is used in the CMS ESRD Core Survey Process, in conjunction with other standard criteria for prioritizing and selecting facilities to survey. In addition, the SHR has been found to be predictive of dialysis facility deficiency citations in the past (ESRD State Outcomes List). The SHR is also a measure that has been publicly reported since January 2013 on the Centers for Medicare and Medicaid Services (CMS) Dialysis Facility Compare Web site.

Overview of Measure

The SHR measure is an NQF-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The Measures Application Partnership supports the direction of this measure for inclusion in the ESRD QIP.

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[5] United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

[6] USRDS Annual Data Report (2015).

[7] USRDS Annual Data Report (2015).

[8] United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

We are proposing to adopt a modified version of the SHR currently endorsed by NQF (NQF #1463). We have submitted this modified measure to NQF for endorsement consideration as part of the standard maintenance process for NQF #1463. When we previously proposed the SHR for implementation in the QIP, we received public comments urging us to not rely solely on CMS Medical Evidence Form 2728 as the only source of patient comorbidity data in the risk-adjustment calculations for the SHR measure. These comments correctly stated that incident comorbidity data are collected for all ESRD patients on CMS Form 2728 when patients first become eligible to receive Medicare ESRD benefits, regardless of payer. Although CMS Form 2728 is intended to inform both facilities and us whether one or more comorbid conditions are present at the start of ESRD, "there is currently no mechanism for either correcting or updating patient comorbidity data on CMS' Medical Evidence Reporting Form 2728" (76 FR 70267). Commenters were concerned that risk-adjusting the SHR solely on the basis of comorbidity data from CMS Form 2728 would create access to care problems for patients, because patients typically develop additional comorbidities after they begin chronic dialysis, and facilities would have a disincentive to treat these patients if recent comorbidities were not included in the risk-adjustment calculations (77 FR 67495 through 67496).

In the CY 2013 ESRD PPS proposed rule, we noted that updated comorbidity data could be captured on the ESRD 72x claims form. Some public comments stated that, "reporting comorbidities on the 72x claim could be a huge administrative burden for facilities, including time associated with validating that the data they submit on these claims is valid" (77 FR 67496). In response to these comments, we stated that we would "continue to assess the best means available for risk-adjustment for both the SHR and Standardized Mortality Ratio (SMR) measures, taking both the benefits of the information and the burden to facilities into account, should we propose to adopt these measures in future rulemaking" (77 FR 67496). We proposed to adopt a Comorbidity Reporting Measure for the PY 2016 ESRD QIP. This measure would have allowed us to collect and analyze the updated comorbidity data "to develop risk adjustment methodologies for possible use in calculating the SHR and SMR measures" (78 FR 72208). We chose not to finalize the comorbidity measure "as a result of the significant concerns expressed by commenters (78 FR 72209).

In response to the comments on the SHR when originally proposed, and subsequently the proposed comorbidity reporting measure, we have made revisions to the SHR specifications. The modified SHR that we are currently proposing to adopt beginning with the PY 2020 ESRD QIP includes a risk adjustment for 210 prevalent comorbidities in addition to the incident comorbidities from the CMS Medical Evidence Form 2728. The 210 prevalent comorbidities were identified through review by a Technical Expert Panel (TEP) first convened in late 2015. The details of how the 210 comorbidities were identified are described below. We propose to identify these prevalent comorbidities for purposes of risk adjusting the measure using available Medicare claims data. We believe this approach allows us to address commenters' concerns about increased reporting burden, while also resulting in a more robust risk-adjustment methodology.

Our understanding is that the NQF evaluates measures on the basis of four criteria: importance, scientific acceptability, feasibility, and usability. The validity and reliability of a measure's risk-adjustment calculations fall under the "scientific acceptability" criterion, and Measure Evaluation Criterion 2b4 specifies NQF's preferred approach for risk-adjusting outcome measures (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79434*). Under this approach, patient comorbidities should only be included in risk-adjustment calculations if the following criteria are met: (1) Risk adjustment should be based on patient factors that influence the measured outcome and are present at the start of care; (2) measures should not be adjusted for factors related to disparities in care or the quality of care; (3) risk adjustment factors must be substantially related to the outcome being measured; and (4) risk adjustment factors should not reflect the quality of care furnished by the provider/facility being evaluated. As indicated in the "Inclusion and Exclusion Criteria" subsection below, as well as in the NQF-endorsed measure specifications, the proposed SHR clinical measure includes dialysis patients starting on day 91 of ESRD treatment. Accordingly, we believe that consistent with NQF Measure Evaluation Criterion 2b4, it is appropriate to risk adjust the proposed SHR measure on the basis of incident patient comorbidity data collected on CMS Form 2728 because these comorbidities are definitively present at the start of care (that is, on day 91 of ESRD treatment). The 210 prevalent comorbidities now included for adjustment were also selected with these criteria in mind. Specifically, in developing its recommendations, the TEP was asked to apply the same criteria that the NQF uses to assign risk-adjusters under the approach described above.

Reflecting these criteria, the TEP evaluated a list of prevalent comorbidities derived through the following process. First, the ESRD Hierarchical Comorbidity Conditions (ESRD–HCCs) were used as a starting point to identify ICD–9 diagnosis codes that could be used for risk adjustment. Those individual ICD–9 conditions that comprised the respective ESRD HCCs, with a prevalence of at least 0.1 percent in the patient population, were then selected for analysis to determine their statistical relationship to mortality or hospitalization. This step resulted in 555 diagnoses for comorbidities (out of over 3000 ICD–9 diagnosis codes in the ESRD–HCCs). Next, an adaptive lasso variable selection method was applied to these 555 diagnoses to identify those with a statistically significant relationship to mortality and/or hospitalization ($p<0.05$). This process identified 242 diagnoses. The TEP members then scored each of these diagnoses as follows:

1. Very likely the result of dialysis facility care.
2. Likely the result of dialysis facility care.
3. May or may not be the result of dialysis facility care.
4. Unlikely to be the result of dialysis facility care.
5. Very likely not the result of dialysis facility care.

This scoring exercise aimed at identifying a set of prevalent comorbidities are not likely the result of facility care and therefore potentially are risk adjusters for SHR and SMR. The TEP concluded that comorbidities scored as "unlikely" or "very unlikely the result of facility care" by at least half of TEP members (simple majority) were appropriate for inclusion as risk-adjusters. This process resulted in 210 conditions as risk adjustors. The TEP recommended incorporation of these adjustors in the risk model for the SHR, and CMS concurred.

Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iv) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (that entity currently is NQF).

Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have given due consideration to endorsed measures, including the endorsed SHR (NQF #1463), as well as those adopted by a consensus organization, and we are proposing this measure under the authority of 1881(h)(2)(B)(ii) of the Act. Although the NQF has endorsed a hospitalization measure (NQF #1463), our analyses suggest that incorporating prevalent comorbidities results in a more robust and reliable measure of hospitalization.

We have analyzed the measure's reliability, the results of which are provided below and in greater detail in the SHR Measure Methodology report, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The Inter-Unit Reliability (IUR) was calculated for the proposed SHR using data from 2012 and a "bootstrap" approach, which uses a resampling scheme to estimate the within-facility variation that cannot be directly estimated by the analysis of variance (ANOVA). A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

Overall, we found that IURs for the 1-year SHRs have a range of 0.70 through 0.72 across the years 2010, 2011, 2012 and 2013, which indicates that two-thirds of the variation in the 1-year SHR can be attributed to the between-facility differences and one-third to within-facility variation.

TABLE 9—IUR FOR 1-YEAR SHR, OVERALL AND BY FACILITY SIZE, 2010–2013

Facility size (number of patients)	2010		2011		2012		2013	
	IUR	N	IUR	N	IUR	N	IUR	N
All	0.72	5407	0.71	5583	0.70	5709	0.70	5864
Small (<=50)	0.54	1864	0.51	1921	0.48	1977	0.46	2028
Medium (51–87)	0.65	1702	0.63	1785	0.58	1825	0.57	1930
Large (>=88)	0.81	1841	0.81	1877	0.81	1907	0.82	1906

We also tested the SHR for measure validity, assessing its association with established quality metrics in the ESRD dialysis population. The SHR measure is correlated with the SMR for each individual year from 2010 through 2013, where Spearman's correlation coefficient ranged from 0.27 to 0.30, with all four correlations being highly significant ($p<0.0001$). Also for each year from 2011 through 2013, the SHR was correlated with the Standardized Readmission Ratio (SRR) (Spearman's rho=0.54, 0.50, 0.48; $p<0.0001$).

In addition, SHR is negatively correlated in each of the 4-years with the measure assessing percentage of patients in the facility with an AV Fistula (Spearman's rho= −0.12, −0.15, −0.12, −0.13). Thus higher values of SHR are associated with lower usage of AV Fistulas. Further, SHR is positively correlated with catheter use >= 90 days (Spearman's rho=0.21, 0.21, 0.18, 0.16), indicating that higher values of SHR are associated with increased use of catheters. These correlations are all highly significant ($p<0.001$). For each year of 2010 through 2013, the SHR is also found to be negatively correlated with the percent of hemodialysis patients with $Kt/V>=1.2$, again in the direction expected (Spearman's rho= −0.11, −0.13, −0.10, −0.11; $p<0.0001$). Lower SHRs are associated with a higher percentage of patients receiving adequate dialysis dose.

Data Sources

Data are derived from an extensive national ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN), which includes Renal Management Information System (REMIS), and the Standard Information Management System database, the Enrollment Database, Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS–2728), transplant data from the Organ Procurement and Transplant Network, the Death Notification Form (Form CMS–2746), the Nursing Home Minimum Dataset, the Dialysis Facility Compare and the Social Security Death Master File. The database is comprehensive for Medicare Parts A and B patients. Non-Medicare patients are included in all sources except for the Medicare payment records. Standard Information Management System/CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations and patient comorbidities are obtained from Medicare Inpatient Claims Standard Analysis Files.

Outcome

The outcome for this measure is the number of inpatient hospital admissions among eligible chronic dialysis patients under the care of the dialysis facility during the 1-year reporting period.

Measure Eligible Population

The measure eligible population includes adult and pediatric Medicare ESRD patients who have reached day 91 of ESRD treatment and who received dialysis within the 1-year period.

Inclusion and Exclusion Criteria

Patients are included in the measure after the first 90 days of treatment. For each patient, we identify the dialysis provider at each point in time. Starting with day 91 of ESRD treatment, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to his or her current facility on day 91 of ESRD treatment if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients are removed from facilities 3 days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

Risk Adjustment

The SHR measure estimates expected hospitalizations calculated from a Cox model that adjusts for patient risk factors and demographic characteristics. This model accounts for clustering of patients in particular facilities and allows for an estimate of the performance of each individual facility, while applying the risk adjustment model to obtain the expected number of hospitalizations for each facility. The model does not adjust for sociodemographic status. We understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding dialysis facilities to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2-years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the Improving Medicare Post-Acute Care Transformation Act. We will closely examine the findings of the Assistant Secretary for Planning and Evaluation reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Calculating the SHR Measure

The SHR measure is calculated as the ratio of the number of observed hospitalizations to the number of expected hospitalizations. A ratio greater than one means that facilities have more hospitalizations than would be expected for an average facility with a similar patient-mix; a ratio less than one means the facility has fewer hospitalizations than would be expected for an average facility with a similar patient-mix.

The SHR uses expected hospital admissions calculated from a Cox model as extended to handle repeated events, with piecewise constant baseline rates. The model is fit in two stages. The stage 1 model is first fitted to the national data with piecewise constant baseline rates applied to each facility. Hospitalization rates are adjusted for patient age, sex, diabetes, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline hospitalization rates to vary between facilities then applies the regression coefficients equally to all facilities. This approach is robust to possible differences between facilities in the patient mix being treated. The second stage then uses a risk adjustment factor from the first stage as an offset. The stage 2 model then calculates the national baseline hospitalization rate. The predicted value from stage 1 and the baseline rate from stage 2 are then used to calculate the expected number of hospital days for each patient over the period during which the patient is seen to be at risk.

The SHR is a point estimate—the best estimate of a facility's hospitalization rate based on the facility's patient- mix. For more detailed information on the calculation methodology please refer to our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We seek comments on our proposal to adopt the SHR measure for the ESRD QIP beginning with PY 2020.

c. Proposed New Reporting Measures Beginning With the PY 2020 ESRD QIP

i. Proposed Serum Phosphorus Reporting Measure

As mentioned above, for PY 2020 we are proposing to adopt a new Proposed Serum Phosphorus Reporting Measure. Section 1881(h)(2)(A)(iii) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calcium-phosphorus dysregulation, which is why we believe that routine blood testing of calcium and phosphorus is necessary to detect abnormalities.

The proposed Serum Phosphorus Reporting Measure is based on a serum phosphorus measure that is endorsed by the NQF (NQF #0255), which evaluates the extent to which facilities monitor and report patient phosphorus levels. In addition, and as explained above, the proposed Serum Phosphorus Reporting Measure is collected using CROWNWeb data and excludes patients using criteria consistent with other ESRD QIP measures. The Measure Applications Partnership expressed full support for this measure.

For PY 2020 and future payment years, we propose that facilities must report serum or plasma phosphorus data to CROWNWeb at least once per month for each qualifying patient. Qualifying patients for this proposed measure are defined as patients 18 years of age or older, who have a completed CMS Medical Evidence Form 2728, who have not received a transplant with a functioning graft, and who are assigned to the same facility for at least the full calendar month (for example, if a patient is admitted to a facility during the middle of the month, the facility will not be required to report for that patient for that month). We further propose that facilities will be granted a one-month period following the calendar month to enter this data. For example, we would require a facility to report Serum Phosphorus rates for January 2018 on or before February 28, 2018. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported. Technical specifications for the Serum Phosphorus reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We seek comments on this proposal.

ii. Proposed Ultrafiltration Rate Reporting Measure

The ultrafiltration rate measures the rapidity with which fluid (ml) is removed during dialysis per unit (kg) of body weight in unit (hour) time. A patient's ultrafiltration rate is under the control of the dialysis facility and is monitored throughout a patient's hemodialysis session. Studies suggest that higher ultrafiltration rates are associated with higher mortality and higher odds of an "unstable" dialysis session,[9] and that rapid rates of fluid removal at dialysis can precipitate events such as intradialytic hypotension, subclinical yet significantly decreased organ perfusion, and in some cases myocardial damage and heart failure.

We have given due consideration to endorsed measures, as well as those adopted by a consensus organization. Because no NQF-endorsed measures or measures adopted by a consensus organization that require reporting of relevant ultrafiltration data currently exist, we are proposing to adopt the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

The proposed Ultrafiltration Rate reporting measure is based upon the NQF-endorsed Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hr) (NQF #2701). This measure assesses the percentage of patient-months for patients with an ultrafiltration rate greater than or equal to 13 ml/kg/hr. The Measure Applications Partnership expressed full support for this measure.

For PY 2020 and future payment years, we propose that facilities must report the following data to CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw submitted to CROWNWeb for that clinical month, for each qualifying patient (defined below):

- HD Kt/V Date
- Post-Dialysis Weight
- Pre-Dialysis Weight
- Delivered Minutes of BUN Hemodialysis
- Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month

Qualifying patients for this proposed measure are defined as patients 18 years of age or older, who have a completed CMS Medical Evidence Form 2728, who have not received a transplant with a functioning graft, who are on in-center hemodialysis, and who are assigned to the same facility for at least the full calendar month (for example, if a patient is admitted to a facility during the middle of the month, the facility will not be required to report for that patient for that month). We further propose that facilities will be granted a one-month period following the calendar month to enter this data. For example, we would require a facility to report ultrafiltration rates for January 2018 on or before February 28, 2018. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported. Technical specifications for the Ultrafiltration Rate reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We seek comments on this proposal.

3. Proposed Performance Period for the PY 2020 ESRD QIP

We are proposing to establish CY 2018 as the performance period for the PY 2020 ESRD QIP for all but the NHSN Healthcare Personnel Influenza Vaccination reporting measure because it is consistent with the performance periods we have historically used for these measures and accounts for seasonal variations that might affect a facility's measure score.

We are proposing that the performance period for the NHSN Healthcare Personnel Influenza Vaccination reporting measure will be from October 1, 2016 through March 31, 2017, because this period spans the length of the 2016–2017 influenza season.

We seek comments on these proposals.

4. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2020 ESRD QIP

Section 1881(h)(4)(A) of the Act provides that "the Secretary shall establish performance standards with respect to measures selected . . . for a performance period with respect to a year." Section 1881(h)(4)(B) of the Act further provides that the "performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary." We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction. We use achievement thresholds and benchmarks to calculate scores on the clinical measures.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2020 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we are proposing for PY 2020 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2016, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2020 program prior to the beginning of the performance period. We continue to believe these standards will provide an incentive for facilities to continuously improve their performance, while not reducing incentives to facilities that score at or above the national performance rate for the clinical measures. We seek comments on these proposals.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2020 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures, because we do not yet have data from CY 2016 or the first portion of CY 2017. We will publish values for the clinical measures, using data from CY 2016 and the first portion of CY 2017, in the CY 2018 ESRD PPS final rule.

c. Proposed Performance Standards for the PY 2020 Reporting Measures

In the CY 2014 ESRD PPS final rule, we finalized performance standards for the Anemia Management and Mineral Metabolism reporting measures (78 FR

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[9] Flythe SE., Kimmel SE., Brunelli SM. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney International (2011) Jan; 79(2):250–7. Flythe JE, Curhan GC, Brunelli SM. Disentangling the ultrafiltration rate—mortality association: The respective roles of session length and weight gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151–61. Movilli, E et al. "Association between high ultrafiltration rates and mortality in uraemic patients on regular hemodialysis. A 5-year prospective observational multicenter study." Nephrology Dialysis Transplantation 22.12(2007): 3547–3552.

72213). We are not proposing any changes to these policies for the PY 2020 ESRD QIP.

In the CY 2016 ESRD PPS final rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66209). We are not proposing any changes to these policies.

For the proposed Ultrafiltration Rate Reporting Measure, we propose to set the performance standard as successfully reporting the following data to CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw for that clinical month, for each qualifying patient (1) HD Kt/V Date; (2) Post-Dialysis Weight; (3) Pre-Dialysis Weight; (4) Delivered Minutes of BUN Hemodialysis; and (5) Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month. This information must be submitted for each qualifying patient in CROWNWeb on a monthly basis, for each month of the reporting period.

For the proposed Serum Phosphorus Reporting measure, we propose to set the performance standard as successfully reporting a serum phosphorus value for each qualifying patient in CROWNWeb on a monthly basis, for each month of the reporting period.

For the proposed NHSN Dialysis Event Reporting measure, we propose to set the performance standard as successfully reporting 12 months of data from CY 2018.

We seek comments on these proposals.

5. Proposal for Scoring the PY 2020 ESRD QIP

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). Under this methodology, facilities receive points along an achievement range based on their performance during the performance period for each measure, which we define as a scale between the achievement threshold and the benchmark. In determining a facility's achievement score for each clinical measure under the PY 2020 ESRD QIP, we propose to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. The facility's achievement score would be calculated by comparing its performance on the measure during CY 2018 (the proposed performance period) to the achievement threshold and benchmark (the 15th and 90th percentiles of national performance on the measure in CY 2016).

We seek comment on this proposal.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2020 ESRD QIP, we propose to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We propose to define the improvement threshold as the facility's performance on the measure during CY 2017. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2018 (the proposed performance period) to the improvement threshold and benchmark.

We seek comment on this proposal.

c. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). We are not proposing any changes to this policy. Under this methodology, facilities will receive an achievement score and an improvement score for each of the three composite measures and three global ratings in the ICH CAHPS survey instrument. A facility's ICH CAHPS score will be based on the higher of the facility's achievement or improvement score for each of the composite measures and global ratings, and the resulting scores on each of the composite measures and global ratings will be averaged together to yield an overall score on the ICH CAHPS clinical measure. For PY 2020, the facility's achievement score would be calculated by comparing where its performance on each of the three composite measures and three global ratings during CY 2018 falls relative to the achievement threshold and benchmark for that measure and rating based on CY 2016 data. The facility's improvement score would be calculated by comparing its performance on each of the three composite measures and three global ratings during CY 2018 to its performance rates on these items during CY 2017.

We seek comments on this proposal.

d. Proposal for Calculating Facility Performance on Reporting Measures

In the CY 2013 ESRD PPS final rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (77 FR 67506). We are not proposing any changes to these policies for the PY 2020 ESRD QIP.

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression Screening and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66210 through 66211). We are not proposing any changes to these policies.

With respect to the proposed Ultrafiltration Rate and Serum Phosphorus reporting measures, we are proposing to score facilities with a CMS Certification Number (CCN) Open Date before July 1, 2018 using the same formula previously finalized for the Mineral Metabolism and Anemia Management reporting measures (77 FR 67506):

$$\left[\frac{(\#\text{ months successfully reporting data})}{(\#\text{ eligible months})}\times 12\right]-2$$

As with the Anemia Management and Mineral Metabolism reporting measures, we would round the result of this formula (with half rounded up) to generate a measure score from 0–10.

We seek comments on these proposals.

6. Proposal for Weighting the Clinical Measure Domain, and Weighting the Total Performance Score

a. Proposal for Weighting the Clinical Measure Domain for PY 2020

In light of the proposed removal of the Safety Subdomain from the Clinical Measure Domain, our policy priorities for quality improvement for patients with ESRD discussed in Section IV.C.6 above, and the criteria finalized in the CY 2015 ESRD PPS Final Rule used to assign weights to measures in a facility's Clinical Measure Domain score (79 FR 66214 through 66216), we propose to weight the following measures in the following subdomains of the proposed clinical measure domain as follows (see Table 10, below):

TABLE 10—PROPOSED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2020 ESRD QIP

Measures/measure topics by subdomain	Measure weight in the clinical domain score (proposed for PY 2020)	Measure weight as percent of TPS (proposed for PY 2020)
Patient and Family Engagement/Care Coordination Subdomain	40%	
ICH CAHPS measure	25%	20%
SRR Measure	15%	12%
Clinical Care Subdomain	60%	
STrR measure	11%	8.8%
Dialysis Adequacy measure	18%	18.8%
Vascular Access Type measure topic	18%	18.8%
Hypercalcemia measure	2%	1.6%
(Proposed) SHR measure	11%	8.8%

Note: We propose that the Clinical Domain make up 80% of a facility's Total Performance Score (TPS) for PY 2020. The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

Specifically, we are proposing to reduce the weight of the Safety Measure Domain in light of validation concerns discussed above in the context of the proposal to reintroduce the NHSN Dialysis Event Reporting Measure (see Section (IV)(1)(a) above). For PY 2020 we are proposing to reduce the weight of the Safety Measure Domain from 15 percent to 10 percent. In future years of the program, we may consider increasing the weight of the NHSN BSI Clinical Measure and/or the NHSN BSI Measure Topic once we see that facilities are completely and accurately reporting to NHSN and once we have analyzed the data from the proposed increased NHSN Data Validation Study. In order to accommodate the reduction of the weight of the Safety Measure Domain, we are proposing to increase the weight of the Clinical Measure Domain to 80 percent, and to keep the weight of the Reporting Measure Domain at 10 percent.

We are also proposing to weight the proposed SHR Clinical Measure at 11 percent of a facility's Clinical Measure Domain score. Facilities have had significant experience with SHR via public reporting on Dialysis Facility Compare, and reducing hospitalizations is a top policy goal for CMS. Further, increasing the emphasis on outcome measures is an additional policy goal of CMS, for reasons discussed above. For these reasons, we believe it is appropriate to weight the proposed SHR Clinical Measure at 11 percent of a facility's Clinical Measure Domain score.

Next, we are proposing to decrease the weight of the Hypercalcemia clinical measure within the Clinical Care Subdomain to 2 percent of a facility's clinical domain score. We are proposing to do so at this time to accommodate the weight assigned to the proposed SHR measure. The Hypercalcemia clinical measure was recently re-endorsed at NQF with a reserved status because there was very little room for improvement and facility scores on the measure are very high overall. Although this is true, the Hypercalcemia clinical measure does not meet the criterion for being topped out in the ESRD QIP (as described in Section IV.D.1. above). Therefore, despite its limited value for assessing facility performance, we decided not to propose to remove the Hypercalcemia clinical measure from the ESRD QIP measure set, but rather to significantly reduce its weight in the clinical subdomain because it provides some indication of the quality of care furnished to patients by facilities.

Finally, to accommodate the proposed addition of the SHR Clinical Measure beginning in PY 2020 and the proposed reduction in weight of the Hypercalcemia measure, we are proposing to reduce the weights of the following measures by 1 percentage point each from what we have proposed for PY 2019, within the Clinical Measure Domain: ICH CAHPS, SRR, STrR, Dialysis Adequacy, and Vascular Access Type. As illustrated in Table 10, these minor reductions in the weights of these measures in the Clinical Measure Domain would be counterbalanced by the increase in the overall percent of the TPS that we are proposing to make to the Clinical Measure Domain, such that the proposed weights for these measures as a percentage of the TPS will remain as constant as possible from PY 2019 to PY 2020. Accordingly, this proposal would generally maintain the percentage of the TPS assigned to these measures.

We seek comments on these proposals.

b. Weighting the Total Performance Score

We continue to believe that while the reporting measures are valuable, the clinical measures evaluate actual patient care and therefore justify a higher combined weight (78 FR 72217). We are proposing to reduce the weight of the Safety Measure Domain from 15 percent of a facility's TPS for PY 2019 to 10 percent of a facility's TPS for PY 2020. As noted in Section IV.C.1.a. above, we are gradually reducing the weight of this Safety Measure Domain over the course of 2 years because we believe it is important to reduce the weight of the Domain in light validation concerns, but it is important to maintain as much consistency as possible in the QIP Scoring Methodology from year to year.

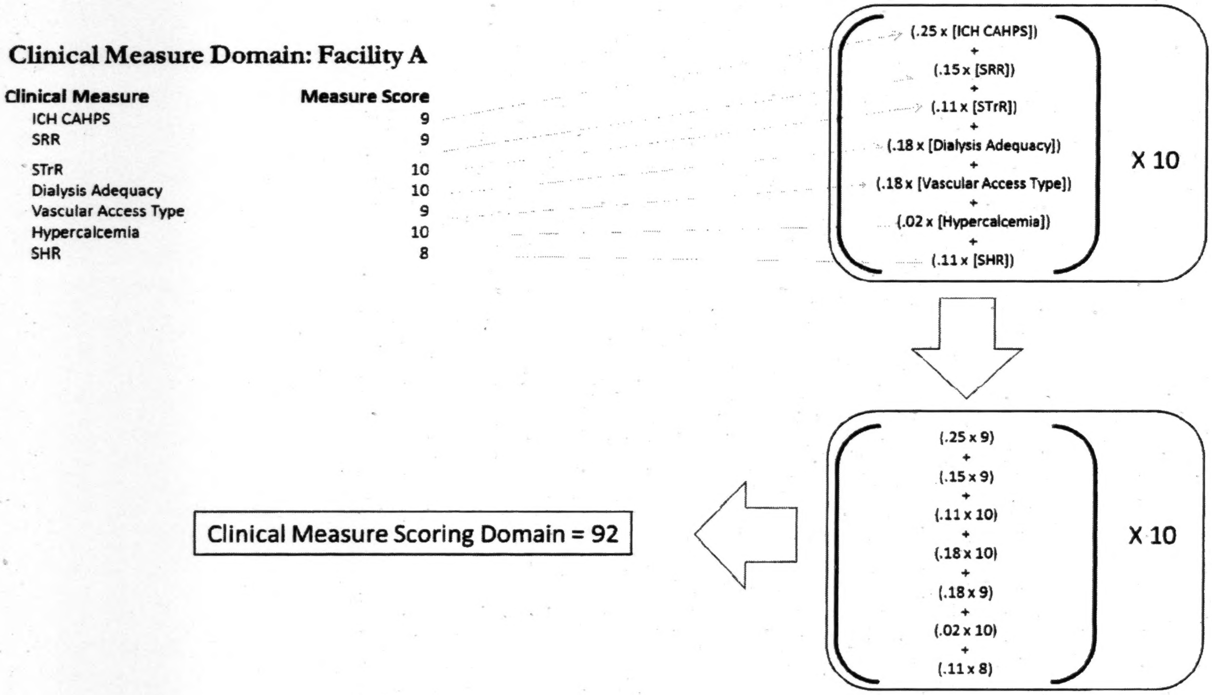
For the same reasons discussed above, in Section IV.C.6., we propose that for PY 2020, to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Measure Domain.

We seek comments on these proposals.

7. Example of the Proposed PY 2020 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the proposed scoring methodology for PY 2020. Figures 6–9 illustrate how to calculate the Clinical Measure Domain score, the Reporting Measure Domain score, the Safety Measure Domain score, and the TPS. Figure 10 illustrates the full proposed scoring methodology for PY 2020. Note that for this example, Facility A, a hypothetical facility, has performed very well. Figure 6 illustrates the methodology used to calculate the Clinical Measure Domain score for Facility A.

FIGURE 6:



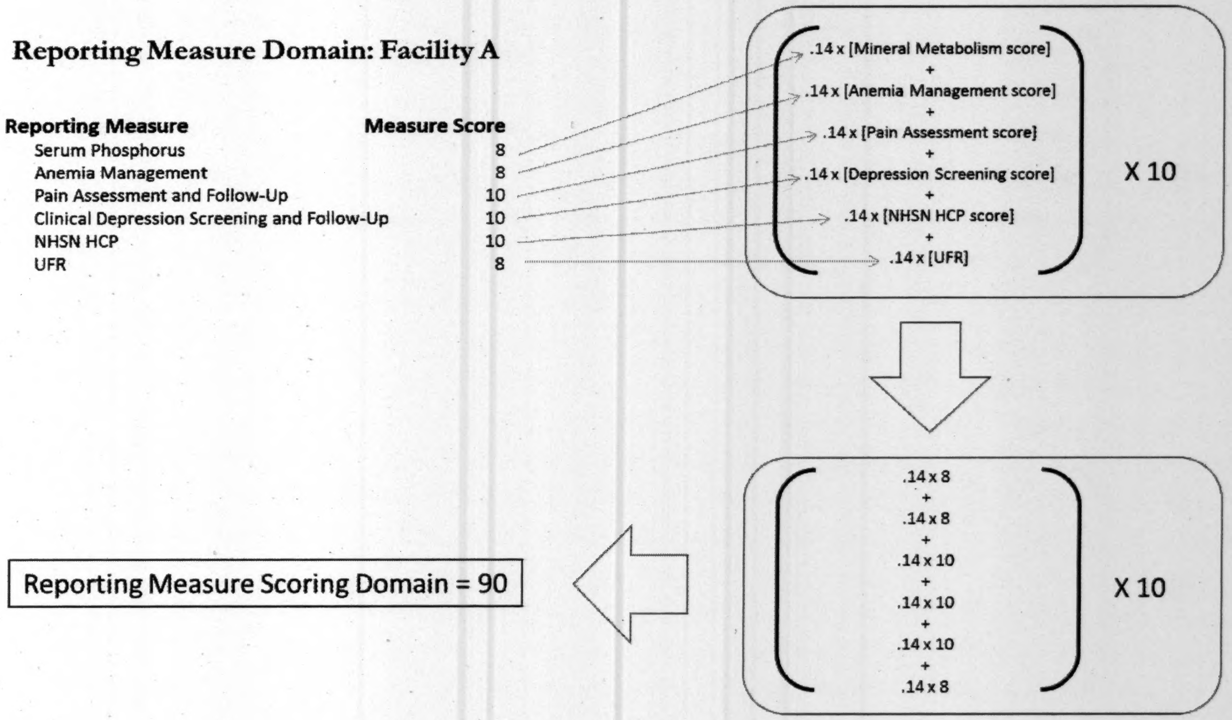
Clinical Measure Domain: Facility A

Clinical Measure	Measure Score
ICH CAHPS	9
SRR	9
STrR	10
Dialysis Adequacy	10
Vascular Access Type	9
Hypercalcemia	10
SHR	8

(.25 x [ICH CAHPS]) + (.15 x [SRR]) + (.11 x [STrR]) + (.18 x [Dialysis Adequacy]) + (.18 x [Vascular Access Type]) + (.02 x [Hypercalcemia]) + (.11 x [SHR])
X 10
(.25 x 9) + (.15 x 9) + (.11 x 10) + (.18 x 10) + (.18 x 9) + (.02 x 10) + (.11 x 8)
X 10
Clinical Measure Scoring Domain = 92

Figure 7 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 7:



Reporting Measure Domain: Facility A

Reporting Measure	Measure Score
Serum Phosphorus	8
Anemia Management	8
Pain Assessment and Follow-Up	10
Clinical Depression Screening and Follow-Up	10
NHSN HCP	10
UFR	8

.14 x [Mineral Metabolism score]
+
.14 x [Anemia Management score]
+
.14 x [Pain Assessment score]
+
.14 x [Depression Screening score]
+
.14 x [NHSN HCP score]
+
.14 x [UFR]
X 10
.14 x 8
+
.14 x 8
+
.14 x 10
+
.14 x 10
+
.14 x 10
+
.14 x 8
X 10
Reporting Measure Scoring Domain = 90

Figure 8 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 8:

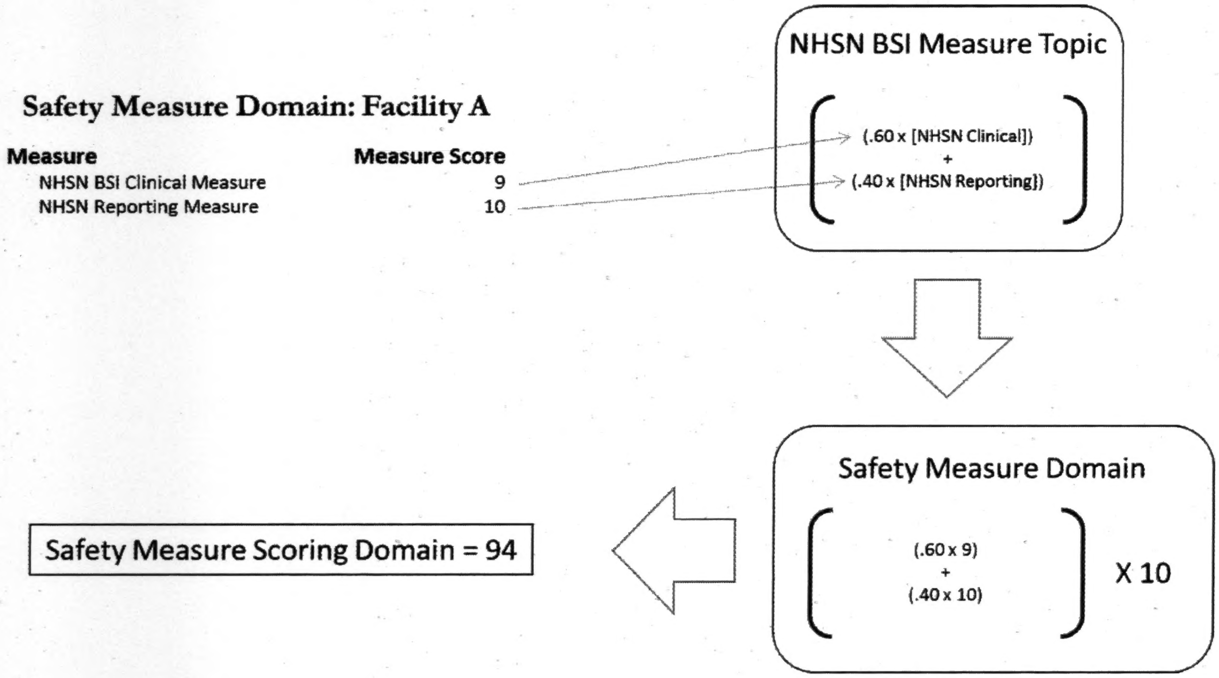
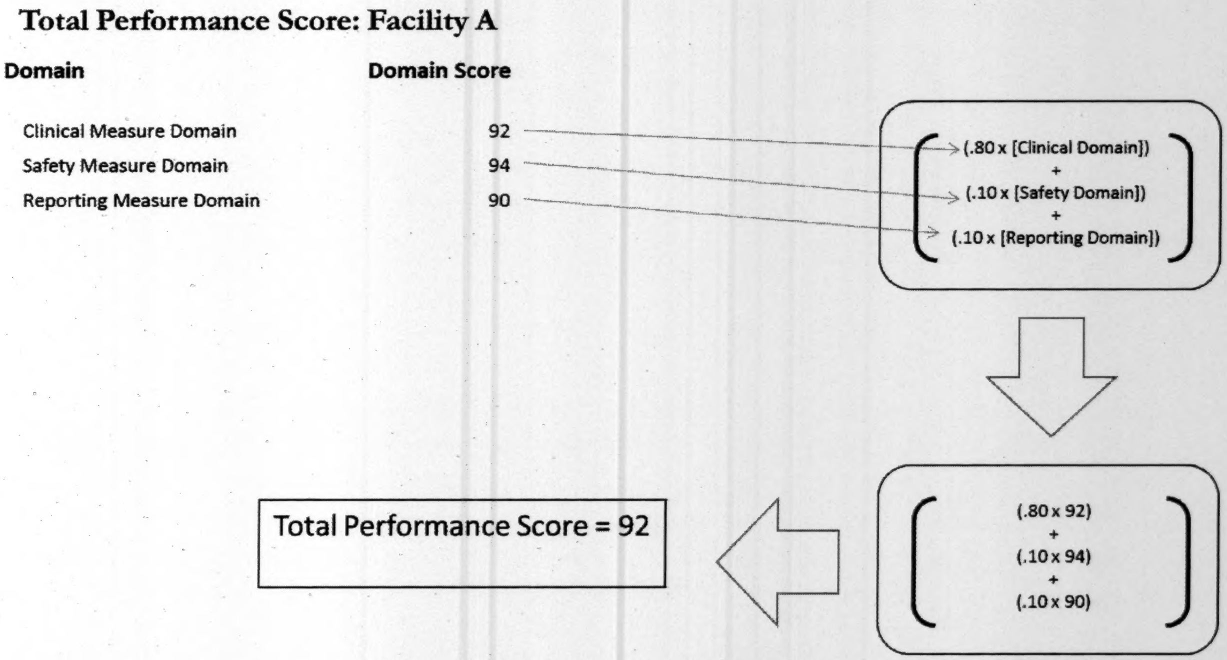

Safety Measure Domain: Facility A
Measure
Measure Score
NHSN BSI Clinical Measure
9
NHSN Reporting Measure
10
NHSN BSI Measure Topic
(.60 x [NHSN Clinical])
+
(.40 x [NHSN Reporting])
Safety Measure Domain
(.60 x 9)
+
(.40 x 10)
X 10
Safety Measure Scoring Domain = 94

Figure 9 illustrates the methodology to calculate the TPS for Facility A.

FIGURE 9:



8. Proposed Minimum Data for Scoring Measures for the PY 2020 ESRD QIP

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period. With the exception of the Standardized Readmission Ratio, Standardized Hospitalization Ratio, Standardized Transfusion Ratio, and ICH CAHPS clinical measures, a facility must treat at least 11 qualifying cases during the performance period in order to be scored on a clinical or reporting measure. A facility must have at least 11 index discharges to be eligible to receive a score on the SRR clinical measure, 10 patient-years at risk to be eligible to receive a score on the STrR clinical measure, and 5 patient-years at risk to be eligible to receive a score on the SHR clinical measure. In order to receive a score on the ICH CAHPS clinical measure, a facility must have treated at least 30 survey-eligible patients during the eligibility period and receive 30 completed surveys during the performance period. We are not proposing to change these minimum data policies for the measures that we have proposed to continue including in the PY 2019 ESRD QIP measure set.

For the proposed Ultrafiltration Rate and Serum Phosphorus Reporting Measures, we also propose that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that setting the case minimum at 11 for these reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly burden or penalize small facilities. We further believe that setting the case minimum at 11 is appropriate because this aligns with case minimum policy for the vast majority of the reporting measures in the ESRD QIP.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's CMS Certification Number (CCN) Open Date. Only facilities with a CCN Open Date before July 1, 2018 would be eligible to be scored on the Anemia Management, Mineral Metabolism, Pain Assessment and Follow-Up, Clinical Depression Screening and Follow-Up reporting measures, and only facilities with a CCN Open Date before January 1, 2018 would be eligible to be scored on the NHSN Bloodstream Infection Clinical Measure, ICH CAHPS Clinical Measure, and NHSN Healthcare Personnel Influenza Vaccination reporting measure. We further propose that, consistent with our CCN Open Date policy for other reporting measures, facilities with a CCN Open Date after July 1, 2018, would not be eligible to receive a score on the Ultrafiltration Rate Reporting Measure because of the difficulties these facilities may face in meeting the requirements of this measure due to the short period of time left in the performance period.

We seek comments on these proposals.

Table 11 displays the proposed patient minimum requirements for each of the measures, as well as the proposed CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 11—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2020 ESRD QIP

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients
Vascular Access Type: Fistula (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	On or before January 1, 2018	11–25 qualifying patients.
NHSN Dialysis Event (Reporting)	11 qualifying patients	On or before January 1, 2018	N/A
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient-years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	On or before January 1, 2018	N/A
Anemia Management (Reporting)	11 qualifying patients	Before July 1, 2018	N/A
Serum Phosphorus (Reporting)	11 qualifying patients	Before July 1, 2018	N/A
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2018	N/A
Pain Assessment and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2017	N/A
NHSN Healthcare Personnel Influenza Vaccination (Reporting).	N/A	Before January 1, 2018	N/A
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before July 1, 2018	N/A

9. Proposed Payment Reductions for the PY 2020 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. We propose that, for the PY 2020 ESRD QIP, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if:

- It performed at the performance standard for each clinical measure; and
- It received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2018 reporting measures.

We note this proposed policy for PY 2020 is identical to the policy finalized for PY 2019.

We recognize that we are not proposing a policy regarding the inclusion of measures for which we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the performance period in the PY 2019 minimum TPS. We have not proposed such a policy because no measures in the proposed PY 2020 measure set meet this criterion. However, should we choose to adopt a clinical measure in future rulemaking without the baseline data required to calculate a performance standard before the beginning of the performance period, we will propose a criterion accounting for that measure in the minimum TPS for the applicable payment year at that time.

The PY 2018 program is the most recent year for which we will have calculated final measure scores before the beginning of the proposed performance period for PY 2020 (that is, CY 2018). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2018 reporting measures. We will publish that value in the CY 2018 ESRD PPS final rule once we have calculated final measure scores for the PY 2018 program.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS final rule (78 FR 72223 through 72224), we finalized a payment reduction scale for PY 2016 and future payment years: for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. We are not proposing any changes to this policy for the PY 2020 ESRD QIP.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. We will publish the minimum TPS, based on data from CY 2016 and the first part of CY 2017, in the CY 2018 ESRD PPS final rule.

We seek comments on this proposal.

E. Future Policies and Measures Under Consideration

As we continue to refine the ESRD QIP's policies and measures, we are evaluating different methods of ensuring that facilities strive for continuous improvement in their delivery of care to patients with ESRD. We also seek to refine our scoring methodology in an effort to make it easier for facilities and the ESRD community to understand. For future rulemaking, we are considering several policies and measures, and we are seeking comments on each of these policies and measures.

As discussed in Section III.D.3.a.i above, we are proposing to adopt the Standardized Hospitalization Ratio (SHR) Clinical measure and calculate performance rates for that measure in accordance with NQF-endorsed, Measures Application Partnership reviewed specifications. Similarly, performance rates for the SRR and STrR will continue to be calculated in accordance with NQF-endorsed, Measures Application Partnership reviewed specifications. Stakeholders have expressed that for most standardized ratio measures, rates are easier to understand than ratios. (The exception is the NHSN BSI Clinical Measure, which is intentionally expressed as a ratio, and cannot be transformed into a rate without distorting the underlying results.) For future years of the QIP, we are considering a proposal to express the ratios as rates instead, for the SRR and STrR measures. Specifically, we would not propose any changes to the manner in which performance rates themselves are calculated, but would propose to calculate rates by multiplying the facility's ratio for each of these measures by the national raw rate of events (also known as the median), which is specific to the measure each year. We are also considering reporting national performance standards and individual facility performance rates as rates, as opposed to ratios, for these measures. Similarly, we are considering a proposal to use rates, as opposed to ratios, when calculating facility improvement scores for these measures.

In PY 2019, we proposed to adopt a patient-level influenza immunization reporting measure that could be used to calculate a future clinical measure based on either "ESRD Vaccination—Full-Season Influenza Vaccination" (MAP #XDEFM) or NQF #0226: "Influenza Immunization in the ESRD Population (Facility Level)." We continue to believe that it is important to include a clinical measure on patient-level influenza vaccination in the ESRD QIP. However, at this time we are not proposing to add a patient-level influenza immunization reporting measure into the ESRD QIP. Nevertheless, data elements were recently amended in CROWNWeb to support data collection for either of the two potential clinical measures on patient-level influenza (that is, MAP # XDEFM and NQF #0226). We will continue to collect these data and conduct detailed analyses to determine whether either of these clinical measures would be appropriate for future inclusion in the ESRD QIP. We are seeking comments on these issues, including whether data for a patient-level influenza immunization clinical measure should be collected through CROWNWeb or through NHSN.

As part of our effort to continuously improve the ESRD QIP, we are also working on developing additional, robust measures that provide valid assessments of the quality of care furnished to ESRD patients by ESRD facilities. Some measures we are considering developing for future inclusion in the ESRD QIP measure set include a Standardized Mortality Ratio (SMR) measure, a measure examining utilization of hospital Emergency Departments, a measure examining medication reconciliation efforts, and a measure examining kidney transplants in patients with ESRD.

We seek comments on these measures and policies that we are considering for adoption in the ESRD QIP in the future.

V. DMEPOS Competitive Bidding Program

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement the CBP in CBAs throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs, mandated by section 1847(a) of the Act, are collectively referred to as the "Medicare DMEPOS Competitive Bidding Program." The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the April 10, 2007 **Federal Register** (72 FR 17992)), established CBPs for certain Medicare Part B covered items of DMEPOS throughout the United States. The CBP, which was phased in over several years, utilizes bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.

Section 1847(a)(1)(G) of the Act, added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA), now requires a bid surety bond for bidding entities.

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of MACRA, provides that, with respect to rounds of competitions under section 1847 beginning not earlier than January 1, 2017 and not later than January 1, 2019, a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of $50,000 to $100,000 in a form specified by the Secretary consistent with subparagraph (H) of section 1847(a)(1), and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s). Section 1847(a)(1)(H)(i) provides that in the event that a bidding entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amount(s) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and CMS will collect on the bid surety bond(s). In instances where a bidding entity does not meet the bid forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidding entity within 90 days of the public announcement of the contract suppliers for such area.

Section 522 of MACRA further amended Section 1847(b)(2)(A) of the Act by adding clause (v) to the conditions that a bidding entity must meet in order for the Secretary to award a contract to any entity under a competition conducted in a CBA to furnish items and services. New clause (v) of section 1847(b)(2)(A) of the Act adds the requirement that the bidding entity must meet applicable State licensure requirements in order to be eligible for a DMEPOS CBP contract award. We note, however, that this does not reflect a change in policy as CMS already requires contract suppliers to meet applicable State licensure requirements in order to be eligible for a contract award.

B. Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Action

This rule proposes to extend our current appeals process for contract terminations to all breach of contract actions that CMS might take. We propose to effectuate this change by expanding the breach of contract actions to which our current appeals process at § 414.423 applies to include all of the breach of contract actions specified in § 414.422(g)(2) and not just § 414.422(g)(2)(iii), which currently describes CMS' ability to terminate a supplier's contract. Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract under our regulations at § 414.422(g)(1). Pursuant to

§ 414.422(g)(2), CMS may take one or more actions in the event that a contract supplier breaches its contract, including, for example, terminating or suspending the contract supplier's contract. We have determined that there are certain actions specified in § 414.422(g)(2) that are not breach of contract actions, such as requiring a contract supplier to submit a corrective action plan and revoking a supplier's billing number under the DMEPOS CBP. We are proposing to remove these two actions from § 414.422(g)(2) . If CMS determines a contract supplier to be in breach of its contract, it will provide a notice of breach of contract to the supplier. Currently, the notice states that a supplier has the right to request a hearing by a Competitive Bidding Implementation Contractor ("CBIC") hearing officer to appeal the termination, but does not specify that there is also a formal process for appealing any of the other breach of contract actions that CMS may take in § 414.422(g)(2). As such, we propose revisions to § 414.422, Terms of Contracts, and § 414.423, Appeals Process for Termination of Competitive Bidding Contract, to extend the appeals process to any breach of contract actions that CMS may take pursuant to the revised § 414.422(g)(2).

C. Provisions of the Proposed Regulations

1. Bid Surety Bond Requirement

At § 414.402, we propose adding a definition for "bidding entity" to mean the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.

At § 414.412, "Submission of bids under a competitive bidding program," we propose to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA. Proposed § 414.412(h)(1) would specify that the bond must be obtained from an authorized surety. An authorized surety is a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.

At proposed § 414.412(h)(2) "Bid Surety Bond requirements," we propose a bid surety bond contain the following information: (1) the name of the bidding entity as the principal/obligor; (2) The name and National Association of Insurance Commissioners number of the authorized surety; (3) CMS as the named obligee; (4) The conditions of the bond as specified in this proposed rule at (h)(3); (5) The CBA covered by the bond; (6) The bond number; (7) The date of issuance; and (8) The bid bond value of $100,000.

Section 1847(a)(1)(G) of the Act permits CMS to determine the amount of the bond within a range of $50,000 to $100,000. Given the importance of this provision, we have determined that it is appropriate to require bidding entities to obtain bid surety bonds in an amount of $100,000 for each CBA in which they submit a bid. This requirement is intended to ensure that bidding entities accept a contract offer(s) when their composite bid(s) is at or below the median composite bid rate used in the calculation of the single payment amounts. We also believe that setting the bid surety bond amount at $100,000 will provide an additional level of assurance that all bidding entities submit substantiated bids. The CBP has historically had a contract acceptance rate exceeding 90 percent, and we believe that this acceptance rate will increase with the promulgation of this regulation. We are considering whether a lower bid surety bond amount would be appropriate for a particular subset of suppliers, for example, small suppliers as defined by § 414.402, and are specifically soliciting comments on whether to establish a lower bid surety bond amount for certain types of suppliers.

Proposed 414.412(h)(3) specifies conditions for forfeiture of the bid surety bond and return of the bond liability. Pursuant to section 1847(a)(1)(H) of the Act, when (1) a bidding entity is offered a contract for any product category in a CBA, (2) the entity's composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category and CBA, and (3) the entity does not accept the contract offer, then the entity's bid surety bond for that CBA will be forfeited and CMS will collect on it. When the bidding entity does not meet these forfeiture conditions, the bid bond liability will be returned within 90 days of the public announcement of the contract suppliers for the CBA. The proposed provision requires CMS to notify a bidding entity when it does not meet the bid forfeiture conditions and as a result CMS will not collect on the bid surety bond.

We propose that bidding entities that provide a falsified bid surety bond would be prohibited from participation in the current round of the CBP in which they submitted a bid and from bidding in the next round of the CBP. Additionally, offending suppliers would be referred to the Office of Inspector General and Department of Justice for further investigation. We also propose that if we find that a bidding entity has accepted a contract offer and then breached the contract in order to avoid bid surety bond forfeiture, the breach would result in a termination of the contract and preclusion from the next round of competition in the CBP. These proposed penalties would be included in our regulations at § 414.412(h)(4).

2. State Licensure Requirement

We propose to revise § 414.414(b)(3), "Conditions for awarding contracts," to align with 1847(b)(2)(A) of the Act as amended by section 522(b) of MACRA. The amendment to the Act states that "[t]he Secretary may not award a contract to any entity under the competition conducted in an [*sic*] competitive acquisition area . . . to furnish such items or services unless the Secretary finds . . . [t]he entity meets applicable State licensure requirements." The regulation at § 414.414 (b)(3) currently states that "[e]ach supplier must have all State and local licenses required to perform the services identified in the request for bids." Therefore, we are proposing to revise 414.414(b)(3)to align with the language of section 1847(b)(2)(A) of the Act as revised by MACRA, to state that a contract will not be awarded to a bidding entity unless the entity meets applicable State licensure requirements. We note, however, that this does not reflect a change in policy as CMS already has a regulation in place to require suppliers to meet applicable State and local licensure requirements.

3. Procedure on Appeals Process for a Breach of Contract of DMEPOS Competitive Bidding Contract Action(s)

We believe suppliers should have the option to appeal all breach of contract actions. As a result, we propose to revise § 414.423, Appeals Process for Termination of Competitive Bidding Contract, to expand the appeals process for suppliers who have been sent a notice of a breach of contract stating that CMS intends to take one or more of the actions described in § 414.422(g)(2) as a result of the breach. While we recognize that we have the authority to take one or more breach of contract actions specified in § 414.422(g)(2), we currently only have an appeals process for one of those actions, specifically, contract termination. Therefore, the proposed revisions will expand § 414.423 to allow appeal rights for each breach of contract action specified in § 414.422(g)(2). If a supplier's notice of breach of contract includes more than one breach of contract action and the supplier chooses to appeal, CMS will make separate decisions for each breach of contract action after reviewing the hearing officer's recommendation. Proposed revisions are made in § 414.422(g)(2) to remove the breach of contract actions of (1) requiring a contract supplier to submit a corrective action plan; and (2) revoking the supplier number of the contract supplier. We are proposing to remove § 414.423(g)(2)(i) because a corrective action plan is a part of the formal appeals process outlined in § 414.423, rather than an action CMS imposes on contract suppliers that it considers to be in breach. We are also proposing to remove the supplier number revocation action at § 414.422(g)(2)(v) because the DMEPOS CBP does not have the authority to revoke a DMEPOS supplier's Medicare billing number. Furthermore, we are proposing to revise this section to state that CMS will specify in the notice of breach of contract which actions they are taking as a result of the breach of contract.

Proposed revisions are made throughout § 414.423 to extend the appeals process to any breach of contract actions described in § 414.422(g)(2) that we might take as a result of the breach, rather than just contract termination actions. We are also proposing to remove the references to termination throughout 414.423 and instead to cross-reference all of the breach of contract actions in § 414.422(g)(2).

In revisions to § 414.423(a), we are proposing to delete the language indicating that termination decisions made under this section are final and binding as this reference is not inclusive of all breach of contract actions, and the finality of a decision is correctly addressed in paragraph (k)(4) of this section.

In the revisions to § 414.423(b)(1), we propose to delete the phrase "either in part or in whole" because 414.422(g)(1) specifies that any deviation from contract requirements constitutes a breach of contract. In addition, we propose to remove the requirement that the breach of contract notice to the supplier be delivered by certified mail from § 414.423(b)(1) to allow CMS the flexibility to use other secure methods for notifying suppliers. We are also proposing changes to § 414.423 (b)(2)(i) and (b)(2)(ii). The revised § 414.423(b)(2)(i) states that the notice of breach of contract will include the details of the breach of contract, while § 414.423(b)(2)(ii) requires CMS to include the action(s) that it is taking as a result of the breach of contract and the timeframes associated with the each breach of contract action in the notice. For example, when a notice of breach of contract includes preclusion, the effective date of the preclusion will be the date specified in the letter and the timeframe of the preclusion will specify the round of the CBP from which the supplier is precluded. We have also added language to (b)(2)(vi) to specify that the effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless a timely hearing request has been filed or a CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

We are proposing to revise § 414.423(c)(2)(ii) to specify that the subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to § 414.423(c)(1)(i). Section 414.423(e)(3) will be revised to clarify that CMS retains the option to offer the supplier an opportunity to submit another CAP, if CMS deems appropriate, in situations where CMS has already accepted a prior CAP.

Proposed revisions to § 414.423(f)(5) explain that in the event the supplier fails to timely request a hearing, the breach of contract action(s) specified in the notice of breach of contract will take effect 45 days from the date of the notice of breach of contract. Proposed revisions to § 414.423(g)(3) will be made to clarify that the scheduling notice must be sent to all parties, not just the supplier.

We are proposing to revise § 414.423(j) to clarify that the hearing officer will issue separate recommendations for each breach of contract action in situations where there is more than one breach of contract action presented at the hearing.

In § 414.423(k), we are proposing to specify that CMS will make separate decisions for each recommendation when the hearing officer issues multiple recommendations. In addition, we are proposing revisions to this paragraph to expand CMS' final determination process, clarifying that the notice of CMS' decision will be sent to the supplier and the hearing officer and will indicate whether any breach of contract actions included in the notice of breach of contract still apply and will be effectuated, and will indicate the effective date of the breach of contract action, if applicable. We propose to expand on § 414.423(l), effect of breach of contract action(s), to specify effects of all contract actions described in § 414.422(g)(2). We propose to add § 414.423(l)(1), effect of contract suspension, to outline the supplier's requirements regarding furnishing items and reimbursement for the duration of the contract suspension, as well as the details regarding the supplier's obligation to notify beneficiaries. We are also proposing to add § 414.423(l)(3), effect of preclusion, to specify that a supplier who is precluded will not be allowed to participate in a specific round of the CBP, which will be identified in the original notice of breach of contract. Additionally, we propose to add § 414.423(l)(4), effect of other remedies allowed by law, to state if CMS decides to impose other remedies under § 414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract. Proposed § 414.423(l) also specifies the steps suppliers must take to notify beneficiaries after CMS takes the contract action(s) described in § 414.422(g)(2). Lastly, we have removed language from § 414.423(l)(2), effect of contract termination, to avoid confusion as to which supplier is providing notice to the beneficiary.

VI. Methodology for Adjusting DMEPOS Fee Schedule Amounts for Similar Items With Different Features Using Information From Competitive Bidding Programs

A. Background

1. Fee Schedule Payment Basis for Certain DMEPOS

Section 1834(a) of the Act governs payment for durable medical equipment (DME) covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule for each of the following categories is established:

- Inexpensive or other routinely purchased items;
- Items requiring frequent and substantial servicing;
- Customized items;
- Oxygen and oxygen equipment;
- Other covered items (other than DME); and
- Other items of DME (capped rental items).

Section 1834(h) of the Act governs payment for prosthetic devices, prosthetics, and orthotics (P&O) and sets forth fee schedule payment rules for P&O. Effective for items furnished on or after January 1, 2002, payment is also made on a national fee schedule basis for parenteral and enteral nutrition (PEN) in accordance with the authority under section 1842(s) of the Act. The term "enteral nutrition" will be used throughout this document to describe enteral nutrients supplies and equipment covered as prosthetic devices in accordance with section 1861(s)(8) of the Act and paid for on a fee schedule basis and enteral nutrients under the Medicare DMEPOS Competitive Bidding Program (CBP), as authorized under section 1847(a)(2)(B) of the Act. Additional background discussion about DMEPOS items subject to section 1834 of the Act, rules for calculating reasonable charges, and fee schedule payment methodologies for PEN and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings, was provided in the July 11, 2014 proposed rule at 79 FR 40275 through 40277.

2. DMEPOS Competitive Bidding Programs Payment Rules

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement CBPs in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the "Medicare DMEPOS Competitive Bidding Program." Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are:

- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DME and medical supplies category includes items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME, but excludes class III devices under the Federal Food, Drug, and Cosmetics Act and Group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished with such wheelchairs. Sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS CBP.

3. Methodologies for Adjusting Payment Amounts Using Information From the DMEPOS Competitive Bidding Program

Below is a summary of the three general methodologies used in adjusting payment amounts for DMEPOS items in areas that are not CBAs for the items using information from the DMEPOS CBP. Also summarized are the processes for updating adjusted fee schedule amounts and for addressing the impact of unbalanced bidding on SPAs when adjusting payment amounts using information from the DMEPOS CBPs. We issued a final rule (Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule) on November 6, 2014 (hereinafter, the CY 2015 final rule) in which we adopted these methodologies (79 FR 66223–66233). We also issued program instructions on these methodologies in Transmittal #3350, (Change Request # 9239), issued on September 11, 2015 and Transmittal #3416, (Change Request # 9431) issued on November 23, 2015. The CBP product categories, HCPCS codes and single payment amounts (SPAs) included in the CBPs are available on the Competitive Bidding Implementation Contractor (CBIC) Web site: *http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home.*

Section 1834(a)(1)(F)(ii) of the Act provides the Secretary with the authority to use information from the DMEPOS CBPs to adjust the DME payment amounts for covered items furnished on or after January 1, 2011, in areas where competitive bidding is not implemented for the items. Similar authority exists at section 1834(h)(1)(H)(ii) of the Act for OTS orthotics. Also, Section 1842(s)(3)(B) of the Act provides authority for making adjustments to the fee schedule amounts for enteral nutrients, equipment, and supplies (enteral nutrition) based on information from CBPs. Section 1834(a)(1)(F)(ii) also requires adjustments to the payment amounts for all DME items subject to competitive bidding furnished in areas where CBPs have not been implemented on or after January 1, 2016.

For items furnished on or after January 1, 2016, section 1834(a)(1)(F)(iii) requires us to continue to make such adjustments to DME payment amounts where CBPs have not been implemented as additional covered items are phased in or information is updated as contracts are re-competed. Section 1834(a)(1)(G) of the Act requires that the methodology used to adjust payment amounts for DME and OTS orthotics using information from the CBPs be promulgated through notice and comment rulemaking. Also, Section 1834(a)(1)(G) of the Act requires that we consider the "costs of items and services in areas in which such provisions [sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii)] would be applied compared to the payment rates for such items and services in competitive acquisition [competitive bidding] areas."

a. Adjusted Fee Schedule Amounts for Areas Within the Contiguous United States

Pursuant to § 414.210(g)(1), CMS determines a regional price for DME items or services for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amounts (SPAs) for an item or service for CBAs that are fully or partially located in the same region that contains the state or the District of Columbia. CMS uses the regional prices to determine a national average price equal to the un-weighted average of the regional prices. The regional SPAs (RSPAs) cannot be greater than 110 percent of the national average price (national ceiling) or less than 90 percent of the national average price (national floor). This methodology applies to enteral nutrition and most DME items furnished in the contiguous United States (that is, items that are included in more than 10 CBAs).

The fee schedule amounts for areas defined as rural areas for the purposes of the CBP are adjusted to 110 percent of the national average price described above. The regulations at § 414.202 define a rural area to mean, for the purpose of implementing § 414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a CBA in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at § 414.210(g) are applied.

b. Adjusted Fee Schedule Amounts for Areas Outside the Contiguous United States

Pursuant to § 414.210(g)(2), in areas outside the contiguous United States (that is, noncontiguous areas such as Alaska, Guam, and Hawaii), the fee schedule amounts are reduced to the greater of the average of SPAs for the item or service for CBAs outside the contiguous United States (currently only applicable to Honolulu, Hawaii) or the national ceiling amounts calculated for an item or service based on RSPAs for CBAs within the contiguous United States.

c. Adjusted Fee Schedule Amounts for Items Included in 10 or Fewer CBAs

Pursuant to § 414.210(g)(3), for DME items included in ten or fewer CBAs, the fee schedule amounts for the items are reduced to 110 percent of the un-weighted average of the SPAs from the ten or fewer CBAs. This methodology applies to all areas within and outside the contiguous United States.

d. Updating Adjusted Fee Schedule Amounts

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information from the CBP to adjust the DMEPOS payment amounts for items furnished on or after January 1, 2016, and section 1834(a)(1)(F)(iii) requires the Secretary to continue to make such adjustments as additional covered items are phased in or information is updated as competitive bidding contracts are recompeted. In accordance with § 414.210(g)(8), the adjusted fee schedule amounts are revised when an SPA for an item or service is updated following one or more new competitions and as other items are added to CBPs. DMEPOS schedule amounts that are adjusted using SPAs will not be subject to the annual DMEPOS covered item update and will only be updated when SPAs from the CBP are updated. Updates to the SPAs may occur at the end of a contract period as contracts are recompeted, as additional items are added to the CBP, or as new CBAs are added. In cases where adjustments to the fee schedule amounts are made using any of the methodologies described above, and the adjustments are based solely on the SPAs from CBPs that are no longer in effect, the SPAs are updated before being used to adjust the fee schedule amounts. The SPAs are adjusted based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) over the course of time described in § 414.210(g)(4). For example, if the adjustments were to be effective January 1, 2017, the SPAs from CBPs no longer in effect would be updated based on the percentage change in the CPI–U from the mid-point of the last year the SPAs were in effect to June 30, 2016, the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustment, if the adjustments continue to be based solely on the SPAs that are no longer in effect, the SPAs will be updated every 12 months using the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

e. Methodology for Avoiding HCPCS Price Inversions When Adjusting Fee Schedule Amounts Using Information From the DMEPOS Competitive Bidding Program

In our CY 2015 final rule (79 FR 66263), we adopted a methodology to address unbalanced bidding, which is a situation that results in price inversions under CBPs. We added § 414.210(g)(6) for certain limited situations where bidding for similar but different enteral infusion pumps and standard power wheelchairs resulted in the SPAs for higher utilized items with additional features (for example, an enteral infusion pump with an alarm or a Group 2 power wheelchair) being less than the SPAs for lower utilized items without those additional features (for example, an enteral infusion pump without an alarm or Group 1 power wheelchair). A Group 2 power wheelchair is faster, travels further, and climbs higher obstacles than a Group 1 power wheelchair. Under CBPs, when similar items with different features are included in the same product category, the code with higher utilization at the time of the competition receives a higher weight and the bid for this item has a greater impact on the supplier's composite bid as well as the competitiveness of the supplier's overall bid for the product category (PC) within the CBP as compared to the bid for the less frequently utilized item. If, at the time the competition takes place under the CBP, the item with the additional features is priced higher and over time is utilized more than the other similar items without these features, it could result in unbalanced bidding, which in turn causes the item without the additional features to receive a higher single payment amount under the CBP than the item with the additional features. This situation results in a price inversion, where the higher weighted and higher priced item at the time of the competition becomes the lower priced item in the CBP following the competition. Unbalanced bidding can occur when a bidder has a higher incentive to submit a lower bid for one item than another due to the fact that the item has a higher weight and therefore a greater effect on the supplier's composite bid for the product category than the other item. Our current regulation at § 414.210(g)(6) for adjusting DMEPOS fee schedule amounts paid in non-CBAs using information from CBPs includes methodologies to address price inversions for power wheelchairs and enteral infusion pumps only. This rule limits SPAs for items without additional features (for example, an enteral infusion pump without an alarm) to the SPAs for items with the additional features (for example, an enteral infusion pump with an alarm) prior to using these SPAs to adjust fee schedule amounts.

For example, if most of the utilization or allowed services for standard power wheelchairs are for higher paying Group 2 wheelchairs than Group 1 wheelchairs at the time the competition occurs, the bids for the Group 2 wheelchairs have a greater impact on the supplier's composite bid and chances of being offered a contract. Therefore the supplier has a much greater incentive to make a lower bid for the Group 2 wheelchairs relative to the fee schedule payment than they do for the Group 1 wheelchairs. If, for example, Medicare is paying $450 per month for a Group 2 wheelchair at the time of the competition and a Group 2 wheelchair has a high weight, while Medicare is paying $350 per month for the Group 1 version of the same wheelchair at the time of the competition and the Group 1 wheelchair has a very low weight, the bids for the two items could be unbalanced or inverted whereby the bid submitted for the Group 2 wheelchair is $250 (44 percent below the fee schedule amount for the item) while the bid submitted for the Group 1 wheelchair is $300 (14 percent below the fee schedule amount for the item). A price inversion therefore results where Medicare previously paid $450 for one item and now pays $250, and previously paid $350 for another item for which it now pays $300. The item weight under the CBP results in Medicare paying more for a Group 1 power wheelchair than a higher-performing Group 2 power wheelchair.

In the CY 2015 proposed rule published on July 11, 2014 in the **Federal Register** (79 FR 40208) (hereinafter, CY 2035 proposed rule), we referred to an additional feature that one item has and another item does not have as a "hierarchal" feature, meaning that one item provides an additional, incremental service that the other item does not provide (79 FR 40287). For example, code B9002 in the HCPCS describes an enteral infusion pump with an alarm, while code B9000 describes an enteral infusion pump without an alarm. Code B9002 describes an item that provides an additional service (an alarm) and the alarm was referred to as a hierarchal feature, meaning the item with the alarm provides an item and service above what the item without the alarm provides. Commenters believed the term "hierarchal feature" should be better defined (79 FR 66231). We agreed and finalized the rule only for the specific scenarios addressed in the proposed rule, namely, enteral infusion pumps and standard power wheelchairs. The final regulation at 42 CFR 414.210(g)(6)(i) specifically requires that in situations where a SPA for an enteral infusion pump without alarm is greater than the SPA in the same CBA for an enteral infusion pump with alarm, the SPA for the enteral infusion pump without alarm is adjusted to equal the SPA for the enteral infusion pump with alarm prior to applying the payment adjustment methodologies for these items in non-CBAs. We also adopted regulations at 42 CFR 414.210(g)(6)(ii) through (v) to address bid inversion for standard power wheelchairs. In the CY 2015 final rule at 79 FR 66231, we stated that we would consider whether to add a definition of hierarchal feature, or to apply the rule we proposed to other items not identified in the final rule through future notice and comment rulemaking.

B. Current Issues

We performed a review of all HCPCS codes in the CBPs in order to comply with our commitment to consider whether to apply the regulation at § 414.210(g)(6) to other cases of price inversion that resulted from unbalanced bidding that were not identified or addressed in the CY 2015 final rule (79 FR 66231). We found a significant number of price inversions resulting from the 2016 DMEPOS CBP Round 2 Recompete for contract periods beginning July 1, 2016. The items affected included transcutaneous electrical nerve stimulation (TENS) devices, walkers, hospital beds, power wheelchairs, group 2 support surfaces (mattresses and overlays), enteral infusion pumps, and seat lift mechanisms. As a result of our review, we are proposing a rule that will expand the provisions of § 414.210(g)(6) to address these and other price inversions.

To perform our review, we examined instances within the HCPCS where there are multiple codes for an item (for example, a walker) that are distinguished by the addition of features (for example, folding walker versus rigid walker or wheels versus no wheels) which may experience price inversions. Our review included all groupings of similar items with different features within each of the product categories. We have included the HCPCS codes describing groupings of similar items that would be subject to this proposed rule and the features associated with each code below:

ENTERAL INFUSION PUMPS	
B9000	Pump without alarm.
B9002	Pump with alarm.
HOSPITAL BEDS	
E0250	Fixed Height With Mattress & Side Rails.
E0251	Fixed Height With Side Rails.
E0255	Variable Height With Mattress & Side Rails.
E0256	Variable Height With Side Rails.
E0260	Semi-Electric With Mattress & Side Rails.
E0261	Semi-Electric With Side Rails.
E0290	Fixed Height With Mattress.
E0291	Fixed Height.
E0292	Variable Height With Mattress.
E0293	Variable Height.
E0294	Semi-Electric With Mattress.
E0295	Semi-Electric.
E0303	Heavy Duty Extra Wide With Side Rails.
E0302	Extra Heavy Duty Extra Wide With Side Rails.
E0303	Heavy Duty Extra Wide With Mattress & Side Rails.
E0304	Extra Heavy Duty Extra Wide With Mattress & Side Rails.
MATTRESSES AND OVERLAYS	
E0277	Powered mattress.
E0371	Powered overlay.
E0372	Non-powered overlay.
E0373	Non-powered mattress.
POWER WHEELCHAIRS	
K0813	Group 1 Sling Seat, Portable.
K0814	Group 1 Captains Chair, Portable.
K0815	Group 1 Sling Seat.
K0816	Group 1 Captains Chair, Standard Weight.
K0820	Group 2 Sling Seat, Portable.
K0821	Group 2 Captains Chair, Portable.
K0822	Group 2 Sling Seat, Standard Weight.
K0823	Group 2 Captains Chair, Standard Weight.
SEAT LIFT MECHANISMS	
E0627	Electric.
E0628	Electric.
E0629	Non-electric.
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICES	
E0720	Two leads.
E0730	Four leads.
WALKERS	
E0330	Rigid.

E0335	Folding.
E0341	Rigid With Wheels.
E0343	Folding With Wheels.

As shown in Table 12 below, under the 2015 DMEPOS fee schedule, Medicare pays more for walkers with wheels than walkers without wheels. The same is true for walkers that fold as compared to walkers that do not fold. Walkers that are rigid and do not fold are very rarely used and have extremely low utilization, and a walker that folds and has wheels is used much more frequently than a walker that folds but does not have wheels.

TABLE 12—AVERAGE OF 2015 DMEPOS FEE SCHEDULE AMOUNTS FOR PURCHASE OF WALKERS

Code	Item	Average 2015 fee schedule amount[1]	2014 Allowed services
E0130	Rigid Walker without Wheels	$64.97	59
E0135	Folding Walker without Wheels	$78.97	5,053
E0141	Rigid Walker with Wheels	$107.89	455
E0143	Folding Walker with Wheels	$111.69	95,939

[1] Average of 2015 fee schedule amounts for all areas.

Under the DMEPOS CBP, because the folding walker without wheels (E0135) is used more frequently than the rigid walker without wheels (E0130), code E0135 receives a higher weight than code E0130. In addition, under the 2015 fee schedule, Medicare pays more for code E0135 than code E0130. Weights are assigned to individual items (HCPCS codes) within a product category (for example, standard mobility equipment) under the DMEPOS CBP for the purpose of calculating a composite bid for each supplier submitting bids for that product category in a CBA. The weights are based on the beneficiary utilization rate using national data when compared to other items in the same product category. The beneficiary utilization rate of an item captures the total allowed services for the item from Medicare claims submitted for the item on a national basis. A supplier's bid for each item in the product category is multiplied by the weight assigned to the item, and the sum of these calculations equals the supplier's composite bid. Contracts are offered to eligible suppliers with the lowest composite bids. Therefore, the higher the weight for an item in a product category, the more the bid for that item will affect the supplier's composite bid and chances of being offered a contract for that product category. Conversely, the lower the weight for an item in a product category, the less the bid for that item will affect the supplier's composite bid and chances of being offered a contract for that product category.

Similarly, because the folding walker with wheels (E0143) is used more frequently than the rigid walker with wheels (E0141), and more frequently than the walkers without wheels (E0130 and E0135), it receives a higher weight under the DMEPOS CBP than all three codes for the less expensive, less frequently utilized codes with fewer features: E0130, E0135, and E0141. Under the 2015 fee schedule, Medicare pays more for code E0143 than codes E0130 (rigid walkers without wheels), E0135 (folding walkers without wheels) or E0141 (rigid walkers with wheels). Under the Round 2 Recompete, the fact that code E0143 (folding walkers with wheels) received a far greater weight than the other walkers that either did not fold, did not have wheels, or had neither feature resulted in price inversions as illustrated in Table 13 below. The first price inversion involves a rigid walker without wheels (E0130). A rigid walker without wheels has lower fee schedule amounts on average and a lower weight than a folding walker without wheels (E0135), yet under competitive bidding, it has a greater SPA than the folding walker. The second price inversion involves a rigid walker with wheels (E0141), which has lower fee schedule amounts on average and a lower weight than a folding walker with wheels (E0143), but has a greater SPA than the folding walker with wheels under competitive bidding. The third price inversion involves a rigid walker without wheels (E0130), which has a greater SPA than a folding walker with wheels despite having lower fee schedule amounts on average and a lower weight than the folding walker with wheels (E0143).

TABLE 13—ROUND 2 (2016) PRICE INVERSIONS FOR PURCHASE OF WALKERS

Code	Item	2015 Fee[1]	Avg SPA[2]
E0130	Rigid Walker without Wheels	$64.97	$47.23
E0135	Folding Walker without Wheels	$78.97	$43.05
E0141	Rigid Walker with Wheels	$107.89	$75.03
E0143	Folding Walker with Wheels	$111.69	$45.92

[1] Average of 2015 fee schedule amounts for all areas.
[2] Average of Round 2 2016 SPAs.

In all cases, Medicare pays higher payment for walkers with wheels than walkers without wheels under the fee schedule. This differential in payment amounts is significant because it reflects the fact that the walker with wheels has a feature that likely resulted in higher fee schedule amounts for this item, making it more costly than the same type of walker without the addition of wheels. Rather than defining the ability of a walker to fold or the presence of wheels as a "hierarchal" feature, it can simply be noted that under the fee schedule, Medicare pays more for walkers with the ability to fold than walkers without the ability to fold and that Medicare pays more for walkers with wheels than for walkers without wheels. If the items with additional features are more expensive and are also utilized more than the items without the features, a price inversion can result in a CBA due to the item weights and how they factor into the composite bids, as described above. Therefore, we propose to adopt a definition of price inversion in our regulations at 414.402 as any situation where the following occurs: (a) One item in a product category includes a feature that another, similar item in the same product category does not have (for example, wheels, an alarm, or Group 2 performance); (b) the average of the 2015 fee schedule amounts for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and (c) the SPA for the item with the feature is lower than the SPA for the item without that feature. We propose to classify this circumstance as a price inversion under competitive bidding that would be adjusted prior to revising the fee schedule amounts for the items. For this adjustment, we considered two methodologies.

The first methodology we considered for addressing price inversions (method 1) uses the methodologies at 42 CFR 414.210(g)(6) and limits the SPA for the code without the feature to the SPA for the code with the feature before the SPA is used to adjust the fee schedule amounts for the item. For example, under the Round 2 Recompete, the SPA for code E0141 for the South Haven-Olive Branch, MS CBA is $106.52. Code E0143 describes the same type of walker, but code E0143 walkers fold, while code E0141 walkers are rigid and do not fold. However, under the Round 2 Recompete, the SPA for code E0143 (wheeled walkers that fold) for the South Haven-Olive Branch, MS CBA is $44.00, or $62.52 less than the SPA for E0141 (wheeled walkers that do not fold). The average of the 2015 fee schedule amounts for codes E0141 and E0143 are $107.89 and $111.69, respectively. Altogether, since (a) one walker in a product category includes a feature that another, similar walker in the same product category does not have (in this situation, the ability to fold); (b) the average of the 2015 fee schedule amounts for the folding walker (E0143) is higher than the average of the 2015 fee schedule amounts for the rigid walker (EO141); and (c) the SPA for the folding walker ($44.50) is lower than the SPA for the rigid walker ($106.52), these items would meet the proposed definition of a price inversion under the DMEPOS CBP. Under method 1, the SPA of $106.52 for code E0141 in this CBA would be adjusted to the SPA of $44.00 for code E0143 in this CBA, so that $44.00, rather than $106.52, would be used for this CBA in computing the regional price for code E0141 described in § 414.210(g)(1)(i) under the methodology used to adjust the fee schedule amounts for code E0141. To further illustrate how method 1 would work, the 2016 SPAs for codes E0130, E0135, E0141, and E0143 for the Akron, Ohio CBA, and the amounts they would be adjusted to before applying the fee schedule adjustment methodologies are listed in Table 14 below.

TABLE 14—ADJUSTMENT OF 2016 SPAS FOR PURCHASE OF WALKERS FOR AKRON, OH TO ELIMINATE PRICE INVERSIONS WITH METHOD 1

Code	Item	2015 Fee[1]	2016 SPA	Adjusted amount[2]
E0130	Rigid Walker without Wheels	$64.97	$50.85	$44.88
E0135	Folding Walker without Wheels	78.97	44.88	n/a
E0141	Rigid Walker with Wheels	107.89	84.82	48.62
E0143	Folding Walker with Wheels	111.69	48.62	n/a

[1] Average of 2015 fee schedule amounts for all areas.

[2] The SPA would be adjusted to this amount before making adjustments to the fee schedule.

The method 1 approach is currently used for enteral infusion pumps and standard power wheelchairs at § 414.210(g)(6), and each price inversion correction is made for a set of two items, as described in the regulation. For example, § 414.210(g)(6)(ii) states: "In situations where a single payment amount in a CBA for a Group 1, standard, sling/solid seat and back power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, sling/solid seat and back power wheelchair, the single payment amount for the Group 1, standard, sling/solid seat and back power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, sling/solid seat and back power wheelchair prior to applying the payment adjustment methodologies in this section." If method 1 is finalized, we would indicate that additional price inversions involving additional sets of two items to which this rule would be applied would be identified in a table in the preamble of the final rule. An example of such a table is provided below in Table 15 using codes for walkers, seat lift mechanisms, and TENS devices:

TABLE 15—ADDITIONAL PRICE INVERSIONS SUBJECT TO 42 CFR 414.210(G)(6)

Item	Code without feature(s)	Code with feature(s)	Feature(s)	Adjustment
Walker	E0130	E0135	Folding	E0130 SPA adjusted not to exceed (NTE) SPA for E0135.
Walker	E0141	E0143	Folding	E0141 SPA adjusted NTE SPA for E0143.
Walker	E0130	E0143	Folding, Wheels	E0130 SPA adjusted NTE SPA for E0143.
Walker	E0135	E0143	Wheels	E0135 SPA adjusted NTE SPA for E0143.
Seat Lift	E0629	E0627[1]	Powered	E0629 SPA adjusted NTE SPA for E0627.
Seat Lift	E0629	E0628[1]	Powered	E0629 SPA adjusted NTE SPA for E0628.
TENS	E0720	E0730	Two Additional Leads	E0720 SPA adjusted NTE SPA for E0730.

[1] Codes E0627 and E0628 both describe powered electric seat lift mechanisms. Code E0627 describes powered seat lift mechanisms incorporated into non-covered seat lift chairs.

The second methodology we considered and are proposing (method 2) would limit the SPAs in situations where price inversions occur so that the SPAs for all of the similar items, both with and without certain features, are limited to the weighted average of the SPAs for the items based on the item weights assigned under competitive bidding. This approach would factor in the supplier bids for the lower volume and higher volume items. This would establish one payment for similar types of items that incorporates the volume and weights for items furnished prior to the unbalanced bidding and resulting price inversions. To illustrate how method 2 would work, the 2016 SPAs for codes E0130, E0135, E0141, and E0143 for the Vancouver, WA CBA, and the amounts they would be adjusted to before applying the fee schedule adjustment methodologies using the weights from Round 2 Recompete are listed in Table 16 below.

TABLE 16—ADJUSTMENT OF 2016 SPAS FOR PURCHASE OF WALKERS FOR VANCOUVER, WA TO ELIMINATE PRICE INVERSIONS METHOD 2

Code	Item	2015 Fee [1]	2016 SPA	Round 2 recompete item weight %	Adjusted amount [2]
E0130	Rigid Walker without Wheels	$64.97	$51.62	0.1	$45.53
E0135	Folding Walker without Wheels	78.97	47.65	4.8	45.53
E0141	Rigid Walker with Wheels	107.89	81.62	0.5	45.53
E0143	Folding Walker with Wheels	111.69	45.22	94.6	45.53

[1] Average of 2015 fee schedule amounts for all areas.

[2] The SPA would be adjusted to this amount before making adjustments to the fee schedule.

The item weights from the Round 2 Recompete for the four walker codes in this subcategory of walkers in the table above are 0.1 percent for E0130, 4.8 percent for E0135, 0.5 percent for E0141, and 94.6 percent for E0143. The weighted average of the SPA for the four walker codes would be $45.53 ($51.62 × 0.001 + $47.65 × 0.048 + $81.62 × 0.005 + $45.22 × 0.946). This weighted average SPA would be used to adjust the fee schedule amounts for these four codes rather than simply limiting the SPAs for E0135 and E0143 in Table 16 above. This method uses item weights in a product category to adjust the SPA before making adjustments to the fee schedule amount. In accordance with the proposed definition of a price inversion, (a) E0135 and E0143 include features that other, similar walkers in the same product category do not (the ability to fold); (b) the average of the 2015 fee schedule amounts for the folding walkers (E0135 & E0143) are higher than the average of the 2015 fee schedule amounts for the rigid walkers (E0130 & E0141); and (c) the 2016 SPAs for the folding walkers were less than the SPAs for the respective rigid walkers. Therefore, the SPA for code E0130 is higher than the SPA for code E0135, the SPAs for codes E0141 and E0143 were inverted such that the SPA for code E0141 is higher than the SPA for code E0143, and the SPAs for codes E0135 and E0143 were inverted such that the SPA for code E0135 is higher than the SPA for code E0143. Under proposed method 2, these three price inversions would be addressed so that the SPAs for all of the similar items described by codes E0130, E0135, E0141, and E0143 in this CBA would be adjusted to the weighted average of the SPAs for these codes for similar items in this CBA. As a result, the adjusted SPA of $45.53 rather than $51.62, $47.65, $81.62, and $45.22, would be used to compute the regional price for codes E0130, E0135, E0141, and E0143, respectively, using method 2 to adjust the fee schedule amounts for these items and in accordance with § 414.210(g)(1)(i).

Although we believe that both method 1 and method 2 would correct inverted SPAs, method 1 simply limits the amount paid for the item without a feature(s) to the item with the feature(s), while method 2 factors in the SPAs for all of the items. Therefore, if the cost of an item without a feature was actually more than the cost of an item with a feature (for example, for volume discounts for the item with the feature drives the price down below the price for the item without the feature), method 1 would not allow the higher cost of the item without the feature to be factored into the payment made to the suppliers of the items. Therefore, we are proposing to use method 2 because it takes into account the supplier bids for all of the similar items into account in establishing the payment amounts used to adjust fees; and therefore, factors in contemporary information relative to bids and supplier information for various items with different features and costs. The SPAs established based on supplier bids for all of the similar items are used to calculate the weighted average. If, for some reason, the market costs for an item without a feature are actually higher than the market costs for an item with the feature, due to economies of scale, supply and demand, or other economic factors, these costs are accounted for in the weighted average of the SPAs established for each of the similar items. Under method 1, the SPA for the lower weight item without a feature is limited to the SPA for the higher weight item with the feature, and so potential cost inversions driven by market forces or supplier costs are not accounted for in establishing the adjusted payment amounts. However, we are soliciting comments on both method 2, which we are proposing, and method 1, which we are considering.

Other examples of price inversions resulting from the Round 2 Recompete are listed in Table 17 below. This is not an exhaustive list of price inversions that have resulted under the CBPs and to which the proposed rule would apply.

TABLE 17—EXAMPLES OF ROUND 2 RECOMPETE SPA PRICE INVERSIONS FOR ITEMS WITH ADDITIONAL FEATURE(S), BY CBA

Higher priced item under 2015 fee schedule	Lower priced item under 2015 fee schedule	Number of CBAs out of 117 with price inversion
Folding Walker with Wheels (E0143)	Rigid Walker with Wheels (E0141)	117 CBAs in which E0143 now priced lower than E0141.
Powered Group 2 Support Surface Mattress (E0277).	Non-powered Group 2 Support Surface Mattress (E0373).	117 CBAs in which E0277 now priced lower than E0373.
Enteral Pump with Alarm (B9002)	Enteral Pump without Alarm (B9000)	112 CBAs in which B9002 now priced lower than B9000.
Group 2 Power Wheelchair (K0823)	Group 1 Power Wheelchair (K0816)	103 CBAs in which K0823 now priced lower than K0816.
Four lead TENS (E0730)	Two lead TENS (E0720)	93 CBAs in which E0730 now priced lower than E0720.

In summary, we propose to expand use of the methodology at § 414.210(g)(6) to other situations where price inversions occur under CBPs. First, we propose to revise 42 CFR 414.402 to add the definition of price inversion as any situation where the following occurs:

- One item (HCPCS code) in a grouping of similar items (for example, walkers, enteral infusion pumps or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (for example, wheels, alarm, or Group 2 performance);
- The average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and
- The SPA in any year after and including 2016 for the code with the feature is lower than the SPA for the code without that feature.

Second, we propose to revise § 414.210(g)(6) to specify that, in situations where price inversions occur under a CBP, the SPAs for the items would be adjusted before applying the fee schedule adjustment methodologies under § 414.210(g). We are proposing that the adjustments to the SPAs would be made using method 2 described above. We are proposing changes to the regulation text at 414.210(g)(6) to reflect use of method 2 to adjust the SPAs for all of the similar items where price inversions have occurred, both with and without certain features, so that they are limited to the weighted average of the SPAs for the items in the product category in the CBA before applying the fee schedule adjustment methodologies under § 414.210(g). We propose to apply this rule to price inversions as defined in this proposed rule for the groupings of similar items listed in the Table 18 below. For the purpose of calculating the weighted average at proposed § 414.210(g)(6)(iii), we are proposing to add a definition of "total nationwide allowed services" at § 414.202, to mean the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services. We are proposing to define the weight for each code in a grouping of similar items at § 414.210(g)(6)(iii) for purposes of calculating the weighted average as the proportion of the total nationwide allowed services for the code for claims with dates of service in calendar year 2012 relative to the total nationwide allowed services for each of the other codes in the grouping of similar items for claims with dates of service in calendar year 2012. We are proposing to use data from calendar year 2012 because this is the most recent calendar year that includes data for items furnished before implementation of Round 2 of the CBP and the beginning of the price inversions. The weights reflect the frequency that covered items in a grouping of similar items were furnished in calendar year 2012 on a national basis relative to other items in the grouping.

TABLE 18—GROUPINGS OF SIMILAR ITEMS

Grouping of similar items	HCPCS codes[1]
Enteral Infusion Pumps	B9000, B9002.
Hospital Beds	E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, E0304.
Mattresses and Overlays	E0277, E0371, E0372, E0373.
Power Wheelchairs	K0813, K0814, K0815, K0816, K0820, K0821, K0822, K0823.
Seat Lift Mechanisms	E0627, E0628, E0629.
TENS Devices	E0720, E0730.
Walkers	E0130, E0135, E0141, E0143.

[1] The descriptions for each HCPCS code are available at: *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html.*

We are soliciting comments on this section.

VII. Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items With Different Features Under the DMEPOS Competitive Bidding Program

A. Background on the DMEPOS Competitive Bidding Programs

Medicare pays for most DMEPOS furnished after January 1, 1989, pursuant to fee schedule methodologies set forth in sections 1834 and 1842 of the Social Security Act (the Act). Specifically, subsections (a) and (h) of section 1834 and subsection (s) of section 1842 of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or a fee schedule amount for the item. The regulations implementing these provisions are located at 42 CFR part 414, subparts C and D.

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement CBPs in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. Section 1847(b)(5) of the Act directs the Secretary to base the single payment amount (SPA) for each item or service in each CBA on the bids submitted and accepted in the CBP. For competitively bid items, the SPAs have replaced the fee schedule payment methodology. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity in a CBA unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. This requirement guarantees savings to both the Medicare program and its beneficiaries.

We implemented CBPs in 9 Round 1 metropolitan statistical areas on January 1, 2011, and an additional 91 Round 2 metropolitan statistical areas on July 1, 2013. Bids are submitted during a 60-day bidding period allowing suppliers adequate time to prepare and submit their bids. We then evaluated each submission and awarded contracts to qualified suppliers in accordance with the requirements of section 1847(b)(2) of the Act, § 414.414, which specifies conditions for awarding contracts, and § 414.416, which specifies how single payment amounts are established.

B. Definitions of Item, Item Weight, Product Category and Composite Bid

"Item" is defined in our regulations at 414.402 as a product included in a CBP that is identified by a HCPCS code, which may be specified for competitive bidding, or a combination of codes and/or modifiers, and includes the services directly related to the furnishing of that product to the beneficiary. Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category. A product category is a grouping of similar items that are used to treat a similar medical condition. Pursuant to § 414.414(e)(3), CMS evaluates bids for items within a product category by establishing a composite bid for each supplier and network that submitted a bid for the product category. A composite bid is the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers. Because suppliers bid for multiple items of similar equipment within a product category, the lowest bid for each item will not always be submitted by the same supplier. Evaluating single bids for individual items would not determine which suppliers should be selected to be contract suppliers because different suppliers may submit the lowest bids for different items. We established this provision (72 FR 18040) for using a composite bid as a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category. This allows us to determine which suppliers can offer the lowest expected costs to Medicare for all items in a product category.

To compute the composite bid for a product category, we multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items. The weight of an item is based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. The sum of each supplier's weighted bids for every item in a product category is the supplier's composite bid for that product category. When an item receives a very low weight within its product category, suppliers have little incentive to bid lower for this item because the bids have a minimal effect on the composite bid of the suppliers, whereas the bids for higher weighted items have a significant effect on the supplier's composite bid. This results in price inversions, as discussed further below.

C. Current Issues

As explained in section VI above, price inversions may occur when items that are similar in terms of the general purpose they serve (for example, walkers), but have different features (for example, wheels, folding capability, etc.), fall within the same product category and have different item weights, therefore having varying degrees of influence on a supplier's composite bid. An item in a product category that is rented and/or purchased by beneficiaries more often than another similar item(s) in the product category has a higher item weight than the other similar item(s) in the product category, and typically will have a higher fee schedule amount at the time the competition takes place than the other similar item(s) in the product category. In a price inversion, an SPA is established for the higher volume item with the higher fee schedule amount that is lower than the SPA(s) established for the other similar item(s) that had lower fee schedule amounts at the time the competition took place. For example, prior to the implementation of the Round 2 CBPs in July 2013, the 2013 rental fee schedule amounts in Akron, Ohio for the infrequently furnished Group 1 power wheelchair (K0816) and portable Group 2 power wheelchair (K0821) were significantly lower than the 2013 rental fee schedule amount for the heavily utilized Group 2 power wheelchair (K0823). Table 19 below shows these fee schedule amounts and also includes national data for calendar year 2012 indicating the percentage of claims for all standard power wheelchairs furnished in 2012 attributed to each code.

TABLE 19—2013 RENTAL FEE SCHEDULE AMOUNTS AND 2012 UTILIZATION RATES FOR CERTAIN POWER WHEELCHAIRS IN AKRON, OHIO CBA

Code	2013 Fee	Akron, OH—Fee schedule	Percent of standard power wheelchair utilization in 2012 (national) %
K0816	$471.38	Group 1 Power Wheelchair	0.16
K0821	463.01	Group 2 Portable Power Wheelchair	0.09
K0823	563.26	Group 2 Power Wheelchair	81.7

Because codes K0816 and K0821 had comparatively low utilization and received very low weights within the product category, suppliers had little incentive to bid lower for these items than for K0823, since the bids for K0816 and K0821 had a minimal effect on the suppliers' composite bids, while the bids for K0823 had a significant effect on the suppliers' composite bids. This resulted in the price inversions described in the Table 20 below, whereby the payment rate for code K0816 was 16 percent lower than the SPA for code K0823 before competitive bidding, but 39 percent higher than the SPA for code K0823 after competitive bidding. Similarly, the payment rate for code K0821 was 18 percent lower than the SPA for code K0823 before competitive bidding, but 43 percent higher than the SPA for code K0823 after competitive bidding.

TABLE 20—PRICE INVERSIONS FOR CERTAIN POWER WHEELCHAIRS IN AKRON, OHIO CBA

Code	2013 SPA	Akron, OH—Competitive bidding	Percent of standard power wheelchair utilization in 2015 (national) %
K0816	$374.55	Group 1 Power Wheelchair	7.2
K0821	387.31	Group 2 Portable Power Wheelchair	4.1
K0823	270.00	Group 2 Power Wheelchair	65.9

The 2012 and 2015 utilization percentages above are the national data for all areas, including areas that are not CBAs. As the tables above show, some utilization of standard power wheelchairs shifted from Group 2 non-portable power wheelchairs to less durable and lower performing Group 1 and Group 2 portable power wheelchairs. This results in the beneficiaries receiving items without additional features at a higher SPA price than items with these additional features. It also undermines the purpose of the CBP and savings intended by the Act and implementation of the program.

The true magnitude of the problem of price inversions is best illustrated by data for power wheelchairs furnished in the Round 2 CBAs. Under the Round 2 competitions and contracts that took effect on July 1, 2013, code K0816 received a very low item weight based on the low utilization rate for this item whereas code K0823 received a very high item weight. The average rental fee schedule amount of $471.38 for code K0816 in 2013 decreased to an average SPA of $344.32 under the CBP, a 27 percent decrease. In comparison, the average reduction in the rental payment amount for code K0823 under Round 2 2013 was 49 percent; from an average rental fee schedule amount in 2013 of $563.26 to an average SPA of $287.05.

After the SPAs took effect in the Round 2 CBAs, we found trends indicating increased expenditures or total allowed charges for code K0816 in the Round 2 CBAs, but a decrease in expenditures or total allowed charges for code K0823 in the Round 2 CBAs. Also, under the Round 2 competition, total allowed charges from July 2013 through December 2015 (2.5 years) for K0816 increased by 1,159 percent as compared to the total allowed charges from January 2011 through June 2013 (2.5 years). By comparison, total allowed charges for K0823 for these same time periods and areas decreased by 86 percent. This inversion in both charges and utilization was more pronounced in certain CBAs than others. In the Atlanta-Sandy Springs-Marietta, Georgia CBA, allowed charges for K0816 (SPA = $361.59) increased by 10,239 percent from $8,010 to $828,995, while allowed charges for K0823 (SPA = $281.89) decreased by 87 percent from $11,051,027 to $1,477,062. We found the same phenomenon for hospital beds where utilization of non-electric hospital beds (code E0250) increased by 214 percent in the Round 2 CBAs while utilization of semi-electric beds (code E0260) decreased by 63 percent. Therefore, the data shows that due to unbalanced bidding in various CBAs, item utilization is shifting from certain items to others, and Medicare is now paying more for these items under the CBP than it was before the CBP was implemented for these items in these CBAs. This is an unacceptable outcome because it results in the beneficiary receiving an item with less functionality (for example, a manual hospital bed rather than a semi-electric hospital bed) at a higher cost for both the Medicare program and the beneficiary than the item with more functionality.

D. Proposed Revisions

To avoid the aforementioned price inversions, we are proposing in § 414.412(d)(2), that in situations where we find that a product category includes a grouping of two or more similar items with different features, that we would utilize an alternative to the current bidding methodology that CMS may apply for certain items within product categories for which previous competitions resulted in price inversions. Under this alternative bidding methodology, we will designate one item as the lead item for the grouping for bidding purposes. The item in the grouping with the highest allowed services during a specified base period, as detailed below, will be considered the lead item of the grouping. For purposes of this proposed rule, the lead item bidding method described below only applies to a subset of similar items with different features identified in this rule, as opposed to an entire product category. The supplier's bid for the lead item would be used as the basis for calculating the SPAs for the similar items within that grouping. That is, we would automatically calculate the SPAs for any similar item in the grouping based on the ratio of the average of the similar item's fee schedule amounts for all areas nationwide in 2015, to the average of the lead item's fee schedule amounts for all areas nationwide in 2015. In § 414.412(d)(2), we are proposing to use the fee schedule amounts for 2015 for the purpose of determining the relative difference in fee schedule payments for similar items because we believe they reflect the relative difference in cost for the items under the fee schedule prior to any adjustments being made to the amounts based on information from the CBPs. We found price inversions for groupings of similar items within the following categories: Standard power wheelchairs, walkers, hospital beds, enteral infusion pumps, TENS devices, support surface mattresses and overlays and seat lift mechanisms. These groupings of similar items are a subset of similar items with different features identified in this rule, as opposed to entire product categories.

Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping of similar items with different features (for example, standard power wheelchairs); however, rather than submitting bids for each individual HCPCS code for each item, a supplier would make one bid that should take into account the cost of furnishing all of the similar items. For example, a $300 bid for K0823 would automatically establish the payment amounts for all the other power wheelchairs in the grouping, so that K0816 would be .84 times $300, and K0829 would be 1.58 times $300 (as shown in the Table 21 below). The supplier may have to adjust its initial K0823 bid before deciding on a final bid, depending on the utilization of the lower volume items in the grouping, and its targeted total revenue for the grouping according to its item weights. The supplier would also be educated at the time of bidding that the SPAs for the other similar items would be based on its bid for the lead item, and the supplier is therefore submitting bids for all of these items when bidding on the lead item. Thus, to avoid cases of price inversions, the supplier is submitting a bid for an item (for example, standard power wheelchair), and for lead item bidding purposes, an "item" is a product that is identified by a combination of codes, as described in § 414.402. We also believe that the proposed lead item-focused bidding method would greatly reduce the burden on suppliers of formulating and submitting multiple bids for similar items because it would require less time to enter their bids and would reduce the chances of keying errors when submitting bids. The items subject to this proposed rule would include a broader set of items than those subject to the proposed rule under section VI above. Namely all codes for walkers, hospital beds, and standard power wheelchairs would be subject to this proposed rule and not just those codes for walkers, hospital beds, and standard power wheelchairs where price inversions have already occurred. The lead item bidding method is intended to prevent future price inversions for a grouping of similar items, including codes for items (for example, total electric hospital beds) where price inversions have not occurred thus far, but where we believe price inversions would be likely based on information about the fee schedule amounts and the utilization of these items. By applying the lead item bidding method to all hospital beds, including total electric hospital beds, this prevents price inversions from occurring for all hospital beds. We also believe it is a more efficient method for implementing CBPs and pricing.

To identify the lead item, we propose using allowed services from calendar year 2012 for the first time this bidding method is used for specific items in specific CBAs. We did not observe price inversions under the Round 1 competitions and contracts that were in effect from January 2011 through December 2013. The price inversions began with the Round 2 competitions and contracts that began on July 1, 2013; therefore, we propose using data for allowed services from calendar year 2012 to ensure that the effects of price inversions do not impact the utilization of the various items that is used to identify the lead item. Once this bidding method has been used in all competitions for an item (for example, standard power wheelchairs), we propose that the lead item would be identified for future competitions based on allowed services for the items at the time the subsequent competitions take place rather than the allowed services from calendar year 2012. For example, using allowed services from calendar year 2012 is necessary to identify the lead items initially since utilization of items for years subsequent to 2012 could be affected by the price inversions that began with the Round 2 competitions and contracts on July 1, 2013. Once the lead item bidding method is implemented for a grouping of similar items, and the price inversions are eliminated, utilization of items for years subsequent to the point at which the price inversions are eliminated can be used for the purpose of identifying the lead item because they would not be affected by price inversions. This proposed rule would also help to prevent price inversions in adjusted fee schedule amounts using competitive bidding SPAs. We propose to announce which items would be subject to this bidding method at the start of each competition in each CBA where this bidding method is used.

The following tables 21, 22, and 23 show how the lead item for three groupings of similar items (standard power wheelchairs, walkers, and hospital beds, respectively) would be identified using 2012 allowed services and how the SPAs would be established based on the method described above. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping of similar items. In the charts below, the lead items identified would be the lead items in initial competitions where the lead item bidding method is used. The first proposed category for lead item bidding is standard power wheelchairs.

TABLE 21—LEAD ITEM BIDDING FOR STANDARD POWER WHEELCHAIRS AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
K0823 (lead item)	Group 2 Captains Chair, Standard Weight	1,108,971	$578.51	1.00
K0825	Group 2 Captains Chair, Heavy Duty	122,422	637.40	1.10
K0822	Group 2 Sling Seat, Standard Weight	99,597	574.73	0.99
K0824	Group 2 Sling Seat, Heavy Duty	10,609	696.23	1.20
K0827	Group 2 Captains Chair, Very Heavy Duty	6,683	766.42	1.32
K0814	Group 1 Captains Chair, Portable	6,287	443.98	0.77
K0816	Group 1 Captains Chair, Standard Weight	2,176	484.14	0.84
K0826	Group 2 Sling Seat, Very Heavy Duty	1,063	901.38	1.56
K0821	Group 2 Captains Chair, Portable	1,048	475.55	0.82
K0813	Group 1 Sling Seat, Portable	771	346.83	0.60
K0815	Group 1 Sling Seat	545	505.52	0.87
K0828	Group 2 Sling Seat, Extra Heavy Duty	114	993.20	1.72
K0829	Group 2 Captains Chair, Extra Heavy Duty	105	912.06	1.58
K0820	Group 2 Sling Seat, Portable	46	370.46	0.64

Rather than submitting 14 individual bids for each of the 14 items, the supplier would submit one bid for the lead item. The SPA for lead item K0823 would be based on the median of the bids for this code, following the rules laid out in § 414.416(b) and for calculating rental amounts pursuant to § 414.408(h)(2). The SPAs for the other items would be based on the relative difference in fees for the other items as compared to the lead item. For example, if the SPA for code K0823 is $300.00, the SPA for code K0825 would be equal to $330.00, or $300.00 multiplied by 1.1. Similarly, if the SPA for code K0823 is $300.00, the SPA for code K0816 would be equal to $252.00, or $300.00 multiplied by 0.84. Suppliers submitting bids would be educated in advance that their bid for code K0823 is a bid for all 14 codes and bidding suppliers would factor this into their decision on what amount to submit as their bid for the lead item. This would avoid price inversions and would carry over the relative difference in item weight that establishes Medicare payment amounts for standard power wheelchairs under the fee schedule into the CBPs. The second proposed category for lead item bidding is walkers as shown in Table 22 below. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping.

TABLE 22—LEAD ITEM BIDDING FOR WALKERS AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 purchase fees	Fee relative to lead item
E0143 (lead item)	Folding With Wheels	958,112	$111.69	1.00
E0135	Folding	56,399	78.97	0.71
E0149	Heavy Duty With Wheels	23,144	214.34	1.92
E0141	Rigid With Wheels	6,319	107.89	0.97
E0148	Heavy Duty	4,366	122.02	1.09
E0147	Heavy Duty With Braking & Variable Wheel Resistance	4,066	551.98	4.94
E0140	With Trunk Support	1,483	346.38	3.10
E0144	Enclosed With Wheels & Seat	1,275	305.95	2.74
E0130	Rigid	788	64.97	0.58

Rather than submitting 9 individual bids for each of the 9 items, the supplier would submit one bid for the lead item. The SPA for lead item E0143 would be based on the median of the bids for this code, following the rules laid out in § 414.416(b) and for calculating rental and purchase amounts per § 414.408(f) and (h)(7). We propose to include a new section 414.416(b)(3) that would include the lead item bidding method. The SPAs for the other items would be based on the relative difference in fees for the item compared to the lead item, following the rules for inexpensive or routinely purchased items at § 414.408(f) and (h)(7), and, for E0144, following the rules for capped rental items at § 414.408(h)(1). For example, if the SPA for purchase for code E0143 is $80.00, Medicare payment for rental of E0143 would be $8.00 per month in accordance with § 414.408(h)(7), and the SPA for purchase of E0143 used would be $60.00. The SPAs for code E0135 would be equal to $56.80 ($80.00 multiplied by 0.71), for purchase of a new E0135 walker, $5.68 per month for rental of E0135, and $42.60 for purchase of a used E0135 walker. The SPAs for rental of code E0144 would be equal to $21.92 ($8.00 multiplied by 2.74) for rental months 1 through 3, and $16.44 for rental months 4 through 13. Suppliers submitting bids would be educated in advance that their bid for code E0143 is a bid for all 9 codes and bidding suppliers would factor this into their decision on what amount to submit as their bid for the lead item. This would avoid price inversions and would carry over the relative difference in item weights that establish Medicare payment amounts for walkers under the fee schedule into the CBPs.

The third proposed category for lead item bidding is hospital beds as shown in the Table 23. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping.

TABLE 23—LEAD ITEM BIDDING FOR HOSPITAL BEDS AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
E0260 (lead item)	Semi-Electric With Mattress & Side Rails	2,201,430	$134.38	1.00
E0261	Semi-Electric With Side Rails	109,727	124.20	0.92
E0303	Heavy Duty Extra Wide With Mattress & Side Rails	47,795	284.67	2.12
E0265	Total Electric With Mattress & Side Rails	37,584	185.75	1.38
E0255	Variable Height With Mattress & Side Rails	25,003	108.10	0.80
E0250	Fixed Height With Mattress & Side Rails	15,075	88.95	0.66
E0295	Semi-Electric	15,056	113.78	0.85
E0294	Semi-Electric With Mattress	9,446	119.93	0.89
E0301	Heavy Duty Extra Wide With Side Rails	6,075	252.96	1.88
E0256	Variable Height With Side Rails	4,135	76.53	0.57
E0304	Extra Heavy Duty Extra Wide With Mattress & Side Rails	2,448	737.98	5.49
E0266	Total Electric With Side Rails	1,969	166.51	1.24
E0251	Fixed Height With Side Rails	1,463	68.26	0.51
E0297	Total Electric	957	129.68	0.97
E0296	Total Electric With Mattress	955	148.29	1.10
E0302	Extra Heavy Duty Extra Wide With Side Rails	732	685.28	5.10
E0292	Variable Height With Mattress	305	76.97	0.57
E0293	Variable Height	189	65.29	0.49
E0290	Fixed Height With Mattress	64	67.29	0.50
E0291	Fixed Height	7	48.85	0.36

Rather than submitting 20 individual bids for each of the 20 items, the supplier would submit one bid for the lead item. The SPA for lead item E0260 would be based on the median of the bids for this code, following the rules laid out in § 414.416(b) and for calculating rental amounts per § 414.408(h)(1). The SPAs for the other items would be based on the relative difference in the average of the 2015 fee schedule amounts for the item compared to the lead item. For example, if the SPA for code E0260 is $75.00, the SPA for code E0261 would be equal to $69.00, or $75.00 multiplied by 0.92. Suppliers submitting bids would be educated in advance that their bid for code E0260 is a bid for all 20 codes and bidding suppliers would factor this into their decision on what amount to submit as their bid for the lead item.

The fourth through seventh proposed categories for lead item bidding are as are shown in Table 24, Table 25 and Table 26 below. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping.

TABLE 24—LEAD ITEM BIDDING FOR ENTERAL INFUSION PUMPS AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
B9002 (lead item)	Pump with alarm	265,890	$121.70	1.00
B9000	Pump without alarm	935	115.47	0.95

TABLE 25—LEAD ITEM BIDDING FOR TENS DEVICES AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
E0730 (lead item)	4 lead	267,428	$402.70	1.00
E0720	2 lead	46,238	388.83	0.97

TABLE 26—LEAD ITEM BIDDING FOR SUPPORT SURFACE MATTRESS/OVERLAY AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
E0277 (lead item)	Powered mattress	139,240	$663.22	1.00
E0372	Powered air mattress overlay	2,076	505.82	0.76
E0371	Nonpower mattress overlay	1,444	416.85	0.63
E0373	Nonpowered mattress	716	576.84	0.87

TABLE 27—LEAD ITEM BIDDING FOR SEAT LIFT DEVICES AND RELATIVE DIFFERENCE IN FEES

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
E0627 (lead item)	Electric, in chair	49,162	$372.22	1.00
E0629	Non-electric	5,901	366.70	0.99
E0628	Electric	5,091	372.22	1.00

In summary, we propose to revise § 414.412(d) to add this bidding method as an alternative to the current method for submitting bid amounts for each item in the seven groupings of similar items identified above. Suppliers participating in future CBPs may be required to use this method when submitting bids for these groups of similar items. Also, we propose to revise § 414.416(b) to add the method for calculating SPAs for items within each grouping of similar items based on the SPAs for lead items within each grouping of similar items. We believe that the proposed method would better accomplish the CBP objectives, which include reducing the amount Medicare pays for DMEPOS and limiting the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the CBP (72 FR 17996).

We believe this approach to bidding would safeguard beneficiaries from receiving items with fewer features simply because of the price inversions. We also believe that the proposed lead item bidding method would greatly reduce the burden on suppliers of formulating and submitting multiple bids for similar items because it would require less time to enter bids and would reduce the chances of keying errors when submitting bids. Finally, we believe this approach would safeguard beneficiaries and the Trust Fund from paying higher amounts for items with fewer features.

We are soliciting comments on this section.

VIII. Bid Limits for Individual Items Under the DMEPOS Competitive Bidding Program

A. Background

Under the DMEPOS CBP, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in CBAs based on bids submitted and accepted by Medicare. For competitively bid items, these new payment amounts, referred to as single payment amounts (SPAs), replace the fee schedule payment methodology. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable single payment amount, less any unmet part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. This requirement guarantees savings to both the Medicare program and its beneficiaries. The CBP also includes provisions to ensure beneficiary access to quality DMEPOS items and services: Section 1847 of the Act directs the Secretary to award contracts to entities only after a finding that the entities meet applicable quality and financial standards and beneficiary access to a choice of multiple suppliers in the area is maintained.

We implemented Round 1 of the DMEPOS CBP on January 1, 2011, and the Round 1 Recompete on January 1, 2014. Round 2 of the DMEPOS CBP and the national mail order program were implemented on July 1, 2013, and Round 2 and national mail order Recompete will be implemented on July 1, 2016. The programs phased in under Round 1 and 2 are in place in approximately 100 metropolitan statistical areas (MSAs) throughout the nation, including Honolulu, Hawaii. A 60-day bidding window allows bidders adequate time to prepare and submit their bids. § 414.412 specifies the rules for submission of bids under a CBP. Each bid submission is evaluated and contracts are awarded to qualified suppliers in accordance with the requirements of section 1847(b)(2) of the Act and § 414.414, which specifies conditions for awarding contracts.

Sections 1847(b)(6)(A)(i) and (b)(6)(A)(ii) of the Act provide that payment will not be made under Medicare part B for items and services furnished under a CBP unless the supplier has submitted a bid to furnish those items and has been awarded a contract. Therefore, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract to do so.

B. Adjusting Fee Schedule Amounts and Bid Limits Established Under the Competitive Bidding Program

The April 10, 2007 final rule (Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule) finalized requirements for providers to submit bids under the DMEPOS CBP (§ 414.412(b)) (79 FR 18026). § 414.412 outlines the requirements associated with submitting bids under the competitive bidding process. Furthermore, § 414.412(b)(2) states that the bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of part 414, which is the fee schedule amount. Therefore, under our current policy, bid amounts that are submitted under the CBP cannot exceed the fee schedule amount. Contracts cannot be awarded in a CBA if total payments under the contracts are expected to be greater than what would otherwise be paid. In the preamble of the CY 2015 final rule that implemented the methodologies to adjust fee schedule amounts using information from CBPs, we indicated that the adjusted fee schedule amounts become the new bid limits (79 FR 66232).

Sections 1834(a)(1)(F)(ii) and (iii), 1834(h)(2)(H)(ii), and 1842(s)(3)(B) of the Act mandate adjustments to the fee schedule amounts for certain DMEPOS items furnished on or after January 1, 2016, in areas that are not CBAs, based on information from CBPs. Section 1842(s)(3)(B) of the Act also provides authority for making adjustments to the fee schedule amounts for enteral nutrients, equipment, and supplies (enteral nutrition) based on information from the CBPs. In the CY 2015 final rule (79 FR 66223), we finalized the methodologies for adjusting DMEPOS fee schedule amounts using information from CBPs at § 414.210(g).

C. Current Issues

If the fee schedule amounts are adjusted as new SPAs are implemented under the CBPs, and these fee schedule amounts and subsequent adjusted fee schedule amounts continue to serve as the bid limits under the programs, the SPAs under the programs can only be lower under future competitions because the bidders cannot exceed the bid limits in the CBP. To continue using the adjusted fee schedule amounts as the bid limits for future competitions does not allow SPAs to fluctuate up or down as the cost of furnishing items and services goes up or down over time.

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under the program if total payments to contract suppliers in an area are expected to be more than would otherwise be paid. For the purpose of implementing section 1847(b)(2)(A)(iii) of the Act, we propose to revise § 414.412(b) to use the unadjusted fee schedule amounts (the fee schedule amounts that would otherwise apply if no adjustments to the fee schedule amounts based on information from CBPs had been made) for the purpose of establishing limits on bids for individual items for future competitions (including re-competes). We are proposing this change because we believe the general purpose of the DMEPOS CBP is to establish reasonable payment amounts for DMEPOS items and services based on competitions among suppliers for furnishing these items and services, with bids from suppliers being based in part on the suppliers' costs of furnishing the items and services at that point in time. We believe the intent of the program is to replace unreasonably high fee schedule amounts for DMEPOS items and services with lower, more reasonable amounts as a result of the competitive bidding. We believe that as long as the amounts established under CBPs are lower than the fee schedule amounts that would otherwise apply had the DMEPOS CBP not been implemented, savings will continue to be generated by the programs.

For competitions held thus far for contract periods starting on January 1, 2011, July 1, 2013, January 1, 2014, and July 1, 2016, the unadjusted fee schedule amounts were used as the bid limits for all items in all CBAs, and the SPAs for each subsequent competition were generally lower than the SPAs for the preceding competitions. We believe that competition for contracts under the programs will continue to keep bid amounts low and, together with utilizing unadjusted fee schedule amounts as bid limits, ensure that total payments under the program will be less than what would otherwise be paid. We believe that prices established through the competitions should be allowed to fluctuate both up and down over time as long as they do not exceed the previous fee schedule amounts that would otherwise have been paid if the CBP had not been implemented, and savings below the previous fee schedule amounts are achieved. This would not apply to drugs included in a CBP which would otherwise be paid under Subpart I of part 414 of 42 CFR based on 95 percent of the average wholesale price in effect on October 1, 2003.

In addition, the amount of the SPAs established under the program is only one factor affecting total payments made to suppliers for furnishing DMEPOS items and services. Although the bid limits were created and are used for implementation of section 1847(b)(2)(A)(iii) of the Act, they are not the only factor that affects total payments to suppliers. The DMEPOS CBP is effective in reducing fraud and abuse by limiting the number of entities that can submit claims for payment, while ensuring beneficiary access to necessary items and services in CBAs. Section 1847(b)(5) of the Act requires that payment to contract suppliers be made on an assignment-related basis and limits beneficiary cost sharing to 20 percent of the SPA. We plan to take all of these factors into account before awarding contracts for subsequent competitions in order to determine if total payments to contract suppliers in an area are expected to be less than would otherwise be paid.

D. Summary of Proposed Bid Limits

We are proposing to revise § 414.412(b) to specify that the bids submitted for each individual item of DMEPOS other than drugs cannot exceed the fee schedule amounts established in accordance with sections 1834(a), 1834(h), or 1842(s) of the Act for DME, off-the-shelf (OTS) orthotics, and enteral nutrition, respectively, as if adjustments to these amounts based on information from CBPs had not been made. Specifically, the bid limits for DME would be based on the 2015 fee schedule amounts established in accordance with section 1834(a)(1)(B)(ii) of the Act, prior to application of section 1834(a)(1)(F)(ii) and (iii), but updated for subsequent years based on the factors provided at section 1834(a)(14) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with section 1834(a), without applying the adjustments mandated by section 1834(a)(1)(F)(ii) of the Act. The bid limits for OTS orthotics would also be based on the 2015 fee schedule amounts established in accordance with section 1834(h)(1)(B)(ii) of the Act, prior to application of section 1834(h)(1)(H), but updated for subsequent years based on the factors provided at section 1834(h)(4) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with section 1834(h), without applying the adjustments authorized by section 1834(h)(1)(H) of the Act. The bid limits for enteral nutrients, equipment, and supplies (enteral nutrition) would be based on the 2015 fee schedule amounts established in accordance with section 1842(s)(1) of the Act, prior to application of section 1842(s)(3), but updated for subsequent years based on the factors provided at section 1842(s)(1)(B)(ii) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with section 1842(s)(1), without applying the adjustments authorized by section 1842(s)(3)(B) of the Act.

Finally, with respect to the alternative bidding rules proposed in section VII. above, when evaluating bids for a grouping of similar items in a product category submitted in the form of a single bid for the highest volume item in the grouping, or lead item, we propose to use the weighted average fee schedule amounts for the grouping of similar items in order to establish the bid limit for the purpose of implementing this proposed provision. We are proposing to revise § 414.412(b)(2) to use total nationwide allowed services for all areas for the individual items, initially from calendar year 2012, to weight the fee schedule amount for each item for the purpose of determining a bid limit for the lead item based on the weighted average fee schedule amounts for the entire grouping of similar items. This would ensure that the payment amounts established under the CBPs do not exceed the fee schedule amounts that would otherwise apply to the grouping of similar items as a whole. Table 28 below illustrates the data that would be used to calculate the bid limit for the lead item (code E0143) in the grouping of walkers for a CBA located in the state of Maryland using 2015 fee schedule amounts for illustration purposes. The item weight for each code is based on 2012 total nationwide allowed services for the code divided by total nationwide allowed services for 2012 for all of the codes in the grouping.

TABLE 28—DATA USED TO CALCULATE BID LIMIT FOR LEAD ITEM FOR WALKERS FOR MARYLAND

HCPCS	Features	Total nationwide allowed services for 2012	2015 purchase fees (MD)	Item weight
E0143 (lead item)	Folding With Wheels	958,112	$115.02	0.90734
E0135	Folding	56,399	77.51	0.05341
E0149	Heavy Duty With Wheels	23,144	213.53	0.02192
E0141	Rigid With Wheels	6,319	110.30	0.00598
E0148	Heavy Duty	4,366	121.56	0.00413
E0147	Heavy Duty With Braking & Variable Wheel Resistance.	4,066	549.90	0.00385
E0140	With Trunk Support	1,483	345.08	0.00140
E0144	Enclosed With Wheels & Seat	1,275	304.80	0.00121
E0130	Rigid	788	67.19	0.00075
Total		1,055,952		

Summing the 2015 fee schedule amounts multiplied by the weights for each item results in a bid limit of $117.37 for lead item E0143. Bids submitted for the lead item E0143 for walkers for a CBA located in the state of Maryland would not be able to exceed $117.37 in this example.

We therefore propose to amend § 414.412(b) to establish this method for determining bid limits for lead items identified in accordance with proposed § 414.412(d)(2) in section VII above.

We are soliciting comments on this proposed rule.

IX. Access to Care Issues for DME

A. Background

The Medicare and Medicaid programs generally serve distinct populations, but more than ten million individuals (“dual eligible beneficiaries”) were enrolled in both programs in 2014.[10] As a group, dual eligible beneficiaries comprise a population with complex chronic care needs and functional impairments.[11] Compared to Medicare-only or Medicaid-only beneficiaries, dual eligible beneficiaries are more likely to experience multiple chronic health conditions, mental illness, functional limitations, and cognitive impairments.

Both Medicare and Medicaid cover Durable Medical Equipment (DME), which can be essential to dual eligible beneficiaries' mobility, respiratory function, and activities of daily living. However, the programs' different eligibility, coverage, and supplier rules can impact access to medically-appropriate DME and repairs of existing equipment for the population enrolled in both benefits.

B. Request for Information

CMS seeks to examine how overlapping but differing coverage standards for DME under Medicare and Medicaid may affect access to care for beneficiaries and administrative processes for providers and suppliers. In response to a May 2011 Request for Information, CMS received over one hundred comments from a range of stakeholders regarding 29 areas of program alignment opportunities, including DME.[12] In the intervening years, CMS has continued to engage stakeholders—including beneficiaries, payers, suppliers, and states—to understand opportunities and challenges caused by differing program requirements.

According to stakeholders, a common barrier to DME access stems from conflicting approval processes among Medicare and Medicaid that can leave suppliers uncertain about whether and how either program will cover items. Medicare is the primary payer for DME and other medical benefits covered by both programs. Medicaid typically pays Medicare cost-sharing amounts and may cover DME that Medicare does not, including certain specialized equipment that promotes independent living. Medicaid pays secondary to most other legally liable payers, including Medicare, and requires those payers to pay to the limit of their legal liability before any Medicaid payment is available. Many of the Medicare requirements related to DME, including the definition and scope of the benefit, are mandated by the statute; therefore, we do not have the authority to bypass or alter these requirements. Medicare generally only processes claims after the equipment is delivered. Because suppliers lack assurance regarding how Medicare or Medicaid will cover DME at the point of sale—and dual eligible beneficiaries cannot pay out-of-pocket up front—suppliers may refuse to provide needed DME.

Other barriers may emerge for beneficiaries who have Medicaid first and get DME prior to enrolling in Medicare. Stakeholders report that many individuals may have difficulty getting coverage for repairs on equipment obtained through Medicaid coverage, since Medicare will only pay for repairs after making a new medical necessity determination. Additionally, not all Medicaid-approved DME suppliers are Medicare-approved suppliers, meaning beneficiaries may need to change suppliers after enrolling in Medicare.

CMS seeks to obtain additional information to help target efforts to promote timely access to DME benefits for people dually eligible for Medicare and Medicaid.

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[10] *Data Analysis Brief: Medicare-Medicaid Dual Enrollment from 2006 through 2013*, Medicare-Medicaid Coordination Office (MMCO), Centers for Medicare and Medicaid Services, December 2014 at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-, Medicaid-Coordination-Office/Downloads/DualEnrollment20062013.pdf*.

[11] Overall these individuals have higher prevalence of many conditions (including, but not limited to diabetes, pulmonary disease, stroke, Alzheimer's disease, and mental illness) than their Medicare-only and Medicaid-only peers. Medicare-Medicaid enrollees' health costs are four times greater than all other people with Medicare. Medicare Medicaid Enrollee State Profile: The National Summary—2008, Centers for Medicare and Medicaid Services at *https://www.cms.gov/Medicare-Medicaid-CoordiNation/Medicare-and-Medicaid-CoordiNation/Medicare-Medicaid-CoordiNation-Office/Downloads/2008NationalSummary.pdf*.

[12] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FederalRegisterNoticeforComment052011.pdf*.

Please provide comments on the scope of the following issues related to DME access for dual eligible beneficiaries:

- Obstacles to timely receipt of needed DME and repairs due to conflicting program requirements;
- Challenges or opportunities faced by Medicaid beneficiaries who newly qualify for Medicare, including challenges related to new and preexisting items, repairs, and providers;
- The percentage of Medicare competitive bidding contractors in the state which accept Medicaid;
- The role of prior authorization policies under either program and whether these policies offer suppliers sufficient advance notice regarding coverage;
- Impacts on beneficiaries from delayed access to needed equipment and repairs;
- If access problems are more pronounced for certain categories of equipment, the categories of DME for which the access problems arise the most frequently or are most difficult to resolve;
- Challenges faced by suppliers in meeting different supporting documentation and submission requirements, and
- Other prevalent access challenges due to DME program misalignments.

We also invite feedback regarding potential regulatory or legislative reforms to address DME program misalignments including:

- State Medicaid program policies that promote coordination of benefits and afford beneficiaries full access to benefits;
- Strategies to promote access to timely, effective repairs, including from suppliers who that did not originally furnish the equipment;
- Policies to address challenges faced when beneficiaries transition from Medicaid-only to dual eligible status; and
- Other ways to promote timely DME access for dual eligible beneficiaries, without introducing new program integrity risks or increasing total expenditures in either Medicare or Medicaid.

Please include specific examples when possible while avoiding the transmission of protected information. Please also include a point of contact who can provide additional information upon request.

X. Comprehensive End-Stage Renal Disease Care Model and Future Payment Models

A. Background

CMS seeks input on innovative approaches to care delivery and financing for beneficiaries with end-stage renal disease (ESRD). This input could include ideas related to innovations that would go above and beyond the Comprehensive ESRD Care (CEC) Model with regard to financial incentives, populations or providers engaged, or the scale of change, among other topics. We will consider information received as we develop future payment models in this area, and as we launch solicitation for a second round of entry into the CEC Model to begin on January 1, 2017.

The CEC Model is a CMS test of a dialysis-specific Accountable Care Organization (ACO) model. In the model, dialysis clinics, nephrologists and other providers join together to create an End-Stage Renal Disease Seamless Care Organization (ESCO) to coordinate care for aligned beneficiaries. ESCOs are accountable for clinical quality outcomes and financial outcomes measured by Medicare Part A and B spending, including all spending on dialysis services for their aligned ESRD beneficiaries. This model encourages dialysis providers to think beyond their traditional roles in care delivery and supports them as they provide patient-centered care that will address beneficiaries' health needs, both in and outside of the dialysis clinic.

B. Provisions of the Notice

Section 1115A of the Social Security Act (the Act), as added by section 3021 of the Affordable Care Act, authorizes the Innovation Center to test innovative payment and service delivery models that reduce spending under Medicare, Medicaid or The Children's Health Insurance Program (CHIP), while preserving or enhancing the quality of care. We seek to gather responses to the following questions that will help us to develop and refine innovative payment models related to kidney care.

Questions:

1. How could participants in alternative payment models (APMs) and advanced alternative payment models (AAPMs) coordinate care for beneficiaries with chronic kidney disease and to improve their transition into dialysis?
2. How could participants in APMs and AAPMs target key interventions for beneficiaries at different stages of chronic kidney disease?
3. How could participants in APMs and AAPMs better promote increased rates of renal transplantation?
4. How could CMS build on the CEC Model or develop alternative approaches for improving the quality of care and reducing costs for ESRD beneficiaries?
5. Are there specific innovations that are most appropriate for smaller dialysis organizations?
6. How could primary-care based models better integrate with APMs or AAPMs focused on kidney care to help prevent development of chronic kidney disease in patients and progression to ESRD? Primary-care based models may include patient-centered medical homes or other APMs.
7. How could APMs and AAPMs help reduce disparities in rates of CKD/ESRD and adverse outcomes among racial/ethnic minorities?
8. Are there innovative ways APMs and AAPMs can facilitate changes in care delivery to improve the quality of life for CKD and ESRD patients?
9. Are there specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use in appropriate populations?
10. Are there specific innovations that could most effectively be tested in a potential mandatory model?

For additional information on the Comprehensive ESRD Care Model and how to apply, click on the Request for Applications located on the Innovation Center Web site at: *innovation.cms.gov/initiatives/comprehensive-ESRD-care.*

XI. Technical Correction for 42 CFR 413.194 and 413.215

In the CY 2013 ESRD PPS final rule (77 FR 67520), we revised § 413.89(h)(3) to set forth the percentage reduction in allowable bad debt payment required by section 1861(v)(1)(W) of the Act for ESRD facilities for cost reporting periods beginning during fiscal year 2013, fiscal year 2014 and subsequent fiscal years. We also revised § 413.89(h)(3) to set forth the applicability of the cap on bad debt reimbursement to ESRD facilities for cost reporting periods beginning between October 1, 2012 and December 31, 2012. In addition, in that rule, we removed and reserved § 413.178, since there were revised provisions set out at § 413.89.

As a part of these revisions, we intended to correct the cross-reference in section §§ 413.194 and 413.215 so that § 413.89(h)(3) was referenced instead of § 413.178. We inadvertently omitted the regulations text that would have made those changes. Therefore, in this rule, we are proposing a technical correction to revise the regulations text at §§ 413.194 and 413.215 to correct the cross-reference to the Medicare bad debt reimbursement regulation, so that §§ 413.194 and 413.215 would reference 42 CFR 413.89(h)(3) instead of the current outdated reference to § 413.178.

XII. Advancing Health Information Exchange

HHS has a number of initiatives designed to improve health and health care quality through the adoption of health information technology (health IT) and nationwide health information exchange. As discussed in the August 2013 Statement "Principles and Strategies for Accelerating Health Information Exchange" (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health IT that facilitates the secure, efficient, and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including ESRD facilities.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0 (Roadmap) (available at *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*) which describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system, and a suggested path for moving from the current state to the desired future state. In the near term, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from electronic health records (EHRs). This shared strategy is intended to reflect important actions that both public and private sector stakeholders can take to enable nationwide interoperability of electronic health information such as: (1) Establishing a coordinated governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying privacy and security requirements that enable interoperability.

In addition, ONC has released the 2016 Interoperability Standards Advisory (available at *https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf*), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these "best available standards" into account as they implement interoperable health information exchange across the continuum of care.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures, and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

XIII. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

In section II and III of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2017 as well as the inclusion of Subpart K for AKI. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, this proposed rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

a. Wage Estimates

In the CY 2016 ESRD PPS Final Rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data,[13] are the individuals tasked with submitting measure data to CROWNWeb and NHSN for purposes of the Data Validation Studies rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients.[14] The mean hourly wage of a Medical Records and Health Information Technician is $18.68 per hour. Under OMB Circular 76–A, in calculating direct labor, agencies should not only include salaries and wages, but also "other entitlements" such as fringe benefits.[15] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $25.45 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP.

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[13] *http://www.bls/gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[14] *http://www.bls.gov/ooh/healthcare/registered-nurses.htm.*

[15] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

b. Time Required To Submit Data Based on Proposed Reporting Requirements

In the CY 2016 ESRD PPS Final Rule (80 FR 69070), we estimated that the time required to submit measure data using CROWNWeb is 2.5 minutes per data element submitted, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files such that they meet CROWNWeb's internal data validation requirements.

c. Data Validation Requirements for the PY 2019 ESRD QIP

Section IV.C.8. in this proposed rule outlines our data validation proposals for PY 2019. Specifically, for the CROWNWeb validation, we propose to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility would be required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be approximately $19,088 (750 hours × $25.45/hour) total of approximately $64 ($19,088/300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

Under the proposed data validation study for validating data reported to the NHSN Dialysis Event Module, we propose to randomly select 150 facilities. A CMS contractor will send these facilities requests for medical records for all patients with "candidate events" during the evaluation period. Overall, we estimate that, on average, quarterly lists will include two positive blood cultures per facility, but we recognize these estimates may vary considerably from facility to facility. We estimate that it will take each facility approximately 60 minutes to comply with this requirement (30 minutes from each of the two quarters in the evaluation period). If 150 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 150 hours (150 facilities × 1 hour). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the NHSN data validation would be $3,817.50 (150 hours × $25.45/hour) total of $25.45 ($3,817.50/150 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–NEW).

d. Proposed Ultrafiltration Rate Reporting Measure

We proposed to include, beginning with the PY 2020 ESRD QIP, a reporting measure requiring facilities to report in CROWNWeb an ultrafiltration rate at least once per month for each qualifying patient. We estimate the burden associated with this measure to be the time and effort necessary for facilities to collect and submit the information required for the Ultrafiltration Rate Reporting Measure. We estimated that approximately 6,454 facilities will treat 548,430 ESRD patients nationwide in PY 2020. The Ultrafiltration Rate Reporting Measure requires facilities to report 13 elements per patient per month (156 elements per patient per year) and we estimate it will take facilities approximately 0.042 hours (2.5 minutes) to submit data for each data element. Therefore, the estimated total annual burden associated with reporting this measure in PY 2020 is approximately 3,593,313 hours (548,430 ESRD patients nationwide × 156 data elements/year × 0.042 hours per element), or approximately 553 hours per facility. We anticipate that Medical Records and Health Information Technicians or similar administrative staff will be responsible for this reporting. We therefore believe the cost for all ESRD facilities to comply with the reporting requirements associated with the ultrafiltration rate reporting measure would be approximately $91,449,815.80 (3,593,313 × $25.45/hour), or $14,082.20 per facility. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–NEW).

XV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XVI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is not economically significant within the meaning of section 3(f)(1) of the Executive Order, since it does not meet the $100 million threshold. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2017. The proposed routine updates include the CY 2017 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Other proposed policy changes include implementation of policy related to payment for hemodialysis treatments furnished more than three times per week and changes to the home dialysis training policy. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2017 for renal dialysis services furnished to ESRD patients and to patients with AKI in accordance with section 1861(s)(2)(F) of the Act.

This rule proposes to implement the provisions in TPEA which provide for coverage and payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish would result in a failure to comply with the requirements of the Act, as added by the TPEA.

This rule proposes to implement requirements for the ESRD QIP, including a proposal to adopt a measure set for the PY 2020 program, as directed by section 1881(h) of the Act. Failure to propose requirements for the PY 2020 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2019. In addition, proposing requirements for the PY 2020 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

This rule proposes a requirement for the DMEPOS CBP for bid surety bonds and state licensure in accordance with section 1847 of the Act, as amended by section 522(a) of MACRA. The rule also proposes an appeals process for all breach of contract actions CMS may take.

This rule also proposes a methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from the DMEPOS CBPs, a methodology for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and revising bid limits for individual items under DMEPOS CBP.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately $50 million in payments to ESRD facilities in CY 2017, which includes the amount associated with updates to the outlier thresholds, home dialysis training policy, payment for hemodialysis treatments furnished more than 3 times per week, and updates to the wage index. We are estimating approximately $2.0 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

For PY 2019, we anticipate that the new burdens associated with the collection of information requirements will be approximately $21 thousand, totaling an overall impact of approximately $15.5 million as a result of the PY 2019 ESRD QIP.[16] For PY 2020, we estimate that the proposed requirements related to the ESRD QIP will cost approximately $91 million dollars, and the payment reductions will result in a total impact of approximately $22 million across all facilities, resulting in a total impact from the proposed ESRD QIP of approximately $113 million.

We anticipate that DMEPOS CBP bidding entities will be impacted by the bid surety bond requirement. The state licensure requirement will have no new impact on the supplier community because this is already a basic supplier eligibility requirement at § 414.414(b)(3), and the appeals process for breach of contract actions may have a beneficial, positive impact on suppliers.

Overall, the bid surety bond requirement may have a positive financial impact on the CBP as we anticipate that the requirement will provide an additional incentive for bidding entities to submit substantiated bids. However, there will be an administrative burden for implementation of the bid surety bond requirement for CMS. We expect minimal administrative costs associated with the state licensure and appeals process for breach of DMEPOS CBP contract proposed rules.

We do not anticipate that the proposed DMEPOS Competitive Bidding regulations will have an impact on Medicare beneficiaries.

We estimate that our proposal for a methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from the DMEPOS CBPs, proposed change for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and proposed revision to the bid limits for items under the DMEPOS CBP will have no significant impact on the suppliers, beneficiaries, Part B trust fund and economy as a whole.

B. Detailed Economic Analysis

1. CY 2017 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2016 to estimated payments in CY 2017. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2016 and CY 2017 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used the December 2015 update of CY 2015 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2015 claims to 2016 and 2017 using various updates. The updates to the ESRD PPS base rate are described in section II.B.3 of this proposed rule. Table 29 shows the impact of the estimated CY 2017 ESRD payments compared to estimated payments to ESRD facilities in CY 2016.

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[16] We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The previously finalized aggregate impact of $15.5 million reflects the PY 2019 estimated payment reductions and the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure.

TABLE 29—IMPACT OF PROPOSED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2017 PROPOSED RULE

Facility type	Number of facilities A	Number of treatments (in millions) B	Effect of 2017 changes in outlier policy (%) C	Effect of 2017 changes in wage indexes (%) D	Effect of total 2017 proposed changes (outlier, wage indexes, training adjustment and routine updates to the payment rate)[4] (%) E
All Facilities	6,453	40.0	0.2	0.0	0.5
Type:					
Freestanding	6,022	37.8	0.2	0.0	0.5
Hospital based	431	2.2	0.3	0.1	0.7
Ownership Type:					
Large dialysis organization	4,541	28.6	0.2	0.0	0.5
Regional chain	990	6.2	0.2	0.0	0.6
Independent	568	3.5	0.2	−0.0	0.4
Hospital based[1]	354	1.8	0.3	0.1	0.7
Geographic Location:					
Rural	1,260	6.0	0.2	0.0	0.6
Urban	5,193	34.0	0.2	0.0	0.5
Census Region:					
East North Central	1,045	5.5	0.2	0.0	0.6
East South Central	522	3.0	0.2	−0.1	0.5
Middle Atlantic	702	4.9	0.2	−0.3	0.2
Mountain	368	2.0	0.1	−0.1	0.4
New England	182	1.3	0.2	−0.5	0.1
Pacific[2]	782	5.7	0.1	0.5	1.0
Puerto Rico and Virgin Islands	49	0.3	0.2	−0.2	0.3
South Atlantic	1,458	9.4	0.2	−0.2	0.4
West North Central	469	2.1	0.2	0.0	0.6
West South Central	876	5.8	0.2	0.1	0.7
Facility Size:					
Less than 4,000 treatments[3]	1,211	2.7	0.2	0.0	0.6
4,000 to 9,999 treatments	2,401	11.0	0.2	0.0	0.6
10,000 or more treatments	2,680	26.1	0.2	0.0	0.5
Unknown	161	0.2	0.2	−0.1	0.5
Percentage of Pediatric Patients:					
Less than 2%	6,349	39.7	0.2	0.0	0.5
Between 2% and 19%	44	0.3	0.2	0.1	0.7
Between 20% and 49%	9	0.0	0.0	0.3	0.6
More than 50%	51	0.0	0.0	0.0	0.3

[1] Includes hospital based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

[3] Of the 1,211 ESRD facilities with less than 4,000 treatments, only 396 qualify for the low-volume payment adjustment. The low-volume payment adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low volume facilities is a 0.5 percent increase in payments.

[4] Includes adjustment of training add-on from $50.16 to $95.57 per treatment and a payment rate update of 0.35 percent.

Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.3.c of this proposed rule is shown in column C. For CY 2017, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.2 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2017 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2017 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.5 percent decrease to a 0.5 percent increase due to these proposed updates.

Column E reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed wage index, the effect of the change in the home dialysis training add-on from $50.16 to $95.57 and the effect of the payment rate update. The ESRD PPS payment rate update is 0.35 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2017 of 2.1 percent, the 1.25 percent reduction as required by the section 1881(b)(14)(F)(i)(I) of the Act, and the MFP adjustment of 0.5 percent. We expect that overall ESRD facilities would experience a 0.5 percent increase in estimated payments in 2017. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.1 percent to an increase of 1.0 percent in their 2017 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2017, we estimate that the proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2017 would be approximately $9.7 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.5 percent in CY 2017.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0.5 percent overall increase in the proposed ESRD PPS payment amounts in CY 2017, we estimate that there will be an increase in beneficiary co-insurance payments of 0.5 percent in CY 2017, which translates to approximately $10 million.

e. Alternatives Considered

In section II.B.1 of this proposed rule, we propose payment for hemodialysis furnished more than 3 times per week. We considered not proposing the payment changes; however, without the proposed changes, facilities would continue to be unable to appropriately bill all of the HD treatments they furnish causing the total number of treatments in our claims data to be understated, and thus the improvement to payment and data collection would not be achieved.

In section II.B.2, we propose changes to the home dialysis training add-on based on the average number of hours for PD and HD and weighted by the percentage of total treatments for each modality. We considered an approach to update the current training add-on amount annually using the market basket increase or the wage and price proxy in the market basket. However, under either approach, the increase to the training add-on payment was small and would not incentivize home dialysis training.

2. Proposed Coverage and Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. Effects on ESRD Facilities

We analyzed CY 2015 hospital outpatient claims to identify the number of treatments furnished historically for AKI patients. We identified 7,155 outpatient claims with AKI that also had dialysis treatments that were furnished in CY 2015. Since the data for 2015 is not complete, we inflated the 7,155 treatments by 22 percent to 8,729 treatments. This inflation factor was determined by comparing the 2014 treatment counts submitted and processed by June 30, 2015 to the 2014 treatment counts submitted and processed by January 8, 2015. We then further inflated the 8,729 treatments to 2017 values using estimated population growth for fee-for service non-ESRD beneficiaries. This results in an estimated 8,938 treatments that would now be paid to ESRD facilities for furnishing dialysis to beneficiaries with AKI. Using the CY 2017 proposed ESRD base rate of $231.04 and an average wage index multiplier, we are estimating approximately $2.0 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

Ordinarily, we would provide a table showing the impact of this provision on various categories of ESRD facilities. Because we have no way to project how many patients with AKI requiring dialysis will choose to have dialysis treatments at an ESRD facility, we are unable to provide a table at this time.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing a payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and their physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We anticipate an estimated $2.0 million being redirected from hospital outpatient departments to ESRD facilities in CY 2017 as a result of some AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus continuing to receive those services in the hospital outpatient setting.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the Outpatient Prospective Payment System's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

In section III.B.2 of this proposed rule, we propose policy related to the implementation of section 808(b) of TPEA, which amended section 1834 by adding a new paragraph (r) which provides payment for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. We considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, other adjustments at 1881(b)(14)(D), as well as not paying separately for AKI specific drugs and labs. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate.

3. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2020 ESRD QIP

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS. The methodology that we are proposing to use to determine a facility's TPS for the PY 2020 ESRD QIP is described in sections III.F.6 and III.F.7 of this proposed rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2020 ESRD QIP would apply to ESRD PPS payments made to the facility in CY 2020.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 48 percent or 2,840 of the facilities would likely receive a payment reduction in PY 2020. Facilities that do not receive a TPS are not eligible for a payment reduction.

In conducting our impact assessment, we have assumed that there will be 6,454 dialysis facilities paid through the PPS. Table 30 shows the overall estimated distribution of payment reductions resulting from the PY 2020 ESRD QIP.

TABLE 30—ESTIMATED DISTRIBUTION OF PY 2020 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities
0.0%	3,174	52.8
0.5%	1,576	26.2
1.0%	903	15.0
1.5%	280	4.7
2.0%	81	1.4

Note: This table excludes 477 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a Total Performance Score.

To estimate whether or not a facility would receive a payment reduction in PY 2020, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 31.

TABLE 31—DATA USED TO ESTIMATE PY 2020 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
Vascular Access Type:		
%Fistula	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
%Catheter	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
Kt/V Composite	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
Hypercalcemia	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
Standardized Transfusion Ratio	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
ICH CAHPS Survey	NA	NA.
Standardized Readmission Ratio	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
NHSN Bloodstream Infection	Jan 2014–Dec 2014	Jan 2014–Dec 2014.
SHR	Jan 2013–Dec 2013	Jan 2014–Dec 2014.

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to an estimated minimum Total Performance Score and an estimated payment reduction table that were consistent with the proposals outlined in Section III.G.9 of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2015. Facilities were required to have a score on at least one clinical and one reporting measure in order to receive a Total Performance Score.

To estimate the total payment reductions in PY 2020 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the one-year period between January 2015 and December 2015 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in January 2015 through December 2015 times the estimated payment reduction percentage). For PY 2020, the total payment reduction for all of the 1,996 facilities expected to receive a reduction is approximately $22 million ($21,990,410). Further, we estimate that the total costs associated with the collection of information requirements for PY 2020 described in section VIII.1.b of this proposed rule would be approximately $91,449,815 million for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $113 million ($91,449,815 + $21,990,410 = $113,440,225) in PY 2020, as a result of the PY 2020 ESRD QIP.

Table 32 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2020. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we propose to use for the PY 2020 ESRD QIP, the actual impact of the PY 2020 ESRD QIP may vary significantly from the values provided here.

TABLE 32—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2020

	Number of facilities	*Number of treatments 2015 (in millions)*	*Number of facilities with QIP score*	*Number of facilities expected to receive a payment reduction*	*Payment reduction (percent change in total ESRD payments)*
All Facilities	6,454	40.0	5,977	1,996	−0.24
Facility Type:					
Freestanding	6,023	37.8	5,807	1,943	−0.24

TABLE 32—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2020—Continued

	Number of facilities	*Number of treatments 2015 (in millions)*	*Number of facilities with QIP score*	*Number of facilities expected to receive a payment reduction*	*Payment reduction (percent change in total ESRD payments)*
Hospital-based	431	2.2	170	53	−0.23
Ownership Type:					
Large Dialysis	4,542	28.6	4,403	1,416	−0.22
Regional Chain	989	6.2	923	299	−0.23
Independent	568	3.5	526	241	−0.42
Hospital-based (non-chain)	354	1.8	125	40	−0.23
Facility Size:					
Large Entities	5,531	34.8	5,326	1,715	−0.22
Small Entities [1]	922	5.2	651	281	−0.39
Rural Status:					
(1) Yes	1,261	6.0	1,137	254	−0.16
(2) No	5,193	34.0	4,840	1,742	−0.25
Census Region:					
Northeast	883	6.2	785	324	−0.29
Midwest	1,512	7.6	1,341	451	−0.24
South	2,855	18.2	2,724	953	−0.25
West	1,143	7.6	1,080	234	−0.15
US Territories [2]	61	0.4	47	34	−0.62
Census Division:					
East North Central	1,045	5.5	939	374	−0.29
East South Central	522	3.0	512	162	−0.20
Middle Atlantic	702	4.9	621	277	−0.32
Mountain	368	2.0	334	53	−0.10
New England	183	1.3	165	47	−0.17
Pacific	782	5.7	751	182	−0.17
South Atlantic	1,458	9.4	1,378	547	−0.29
West North Central	469	2.1	402	77	−0.13
West South Central	875	5.8	834	244	−0.20
U.S. Territories [2]	49	0.3	41	33	−0.69
Facility Size (# of total treatments)	1,211	2.7	975	217	−0.17
Less than 4,000 treatments:					
4,000–9,999 treatments	2,402	11.0	2,324	759	−0.24
Over 10,000 treatments	2,680	26.1	2,605	1,003	−0.26
Unknown	161	0.2	73	17	−0.18

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.

[2] Includes Puerto Rico and Virgin Islands.

4. DMEPOS Competitive Bidding Bid Surety Bond, State Licensure and Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions

a. Effects on Competitive Bidding Program Suppliers

Bid Surety Bonds. It is difficult to estimate the precise financial impact the bid surety bond requirement will have on competitive bidding entities as this type of bond is not currently available. Based on our research of the bond industry, as well as the structure of the existing CMS DMEPOS surety bond requirement for all DMEPOS suppliers, we anticipate that the cost to obtain a bid surety bond will be based on a percentage of the total bond amount. This percentage may be adjusted by the authorized surety based upon certain criteria such as: (1) The number of bid surety bonds purchased by a bidding entity, (2) the credit score of the bidding entity and, (3) the prior contracting experience the bidding entity has had with the DMEPOS CBP, that is, history of accepting/rejecting contracts.

For instance, an authorized surety may establish a preliminary charge amount of 2 percent of the total bond amount to obtain a $100,000 bid surety bond. We anticipate that the authorized surety may adjust their charge percentage based on the number of CBAs in which a bidding entity bids, that is, a bulk discount. Bidding entities that purchase multiple bid surety bonds from the authorized surety would likely receive a reduced charge per bid surety bond as compared to a bidding entity that only purchases a single bid surety bond. We also expect that authorized sureties will evaluate each bidding entity's credit score(s) to either establish an appropriate charge percentage or to decide not to issue a bond if the bidding entity's credit score is too low. Lastly, we anticipate that an authorized surety may also request documentation from prior rounds of bidding to understand the bidding entity's experience with contract acceptance. Bidding entities that have accepted more contract offers in the prior round without any contract rejections may be viewed by an authorized surety as less risky than a bidding entity who has rejected numerous contract offers with few or no contract acceptance.

On January 1, 2019, CMS will be combining all CBAs into a consolidated round of competition. As a result, we estimate the aggregate total out of pocket cost for bidding entities to bid in this competition to be $26,000,000. This estimate is based upon the approximately 13,000 distinct bidders for CBAs included in both the Round 2 Recompete and Round 1 2017 multiplied by a $2,000 per bid surety bond price. Given the unknown variables with this new type of bond, we are seeking comments on how the authorized sureties will set the purchase amount for bidding entities in order to finalize a more accurate estimate.

We do anticipate that there will be an impact on small suppliers. We are seeking comments on whether we should have a reduced bid surety bond amount for a particular subset of suppliers, for example, small suppliers as defined by the CBP. In terms of a small supplier obtaining a bond, the Small Business Administration (SBA) has a statement on their Web site stating that their guarantee "encourages surety companies to bond small businesses," and as such we anticipate that small suppliers will be able to reach out to the SBA if they encounter difficulty in obtaining a bond.

As a result of the implementation of this proposed rule, we anticipate that this requirement may deter some suppliers from bidding, which would result in a lower number of bids submitted to the DMEPOS CBP. We are seeking comments on the impact of the bid surety bond requirement on supplier participation in the DMEPOS CBP.

State Licensure. Contract suppliers in the CBP are already required to have the proper state licensure in order to be eligible for a contract award. We do not anticipate that conforming the language of the regulation to the language in section 1847(b)(2)(A), as added by section 522 of MACRA, will have any additional impact beyond what is already being imposed on suppliers.

Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions. We believe the expansion of the appeal rights for breach of contract may have a positive impact on contract suppliers by providing the formal opportunity to appeal any of the actions that CMS may take as a result of a breach of contract.

b. Effects on the Medicare Program

Bid Surety Bonds. We anticipate that the bid surety bond requirement will result in bidding entities being more conscientious when formulating their bid amounts. In addition, given the already high historic contract acceptance rate exceeding 90 percent per round, we anticipate that the bid surety bond provision will result in an even higher rate of contract acceptance.

As a result of the implementation of this proposed rule, we anticipate that this regulation may deter some bidding entities from bidding, which would result in a lower number of bids submitted to the DMEPOS CBP. This reduction could reduce competition and lead to a decreased number of contract suppliers and, as a result, less savings from the program.

Additionally, we expect that there will be an administrative burden for implementing the bid surety bond requirement, which includes educating bidding entities, updating CMS bidding and contracting systems, and verifying that the bonds are valid.

State Licensure. We do not anticipate that conforming the language of the regulation to the language in section 1847(b)(2)(A), as added by section 522 of MACRA, will have any additional impact beyond what is already being imposed on suppliers. Therefore, the burden of meeting this statutory requirement has already been estimated in previous regulations and this proposed rule does not add to the burden.

Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions. We expect that there may be some de minimis costs to expand the appeals process. We anticipate that overall this proposed rule will have a positive impact on the program by allowing suppliers a full appeals process for any breach of contract action that CMS may take pursuant to § 414.422(g)(2).

c. Effects on Medicare Beneficiaries

The proposed CBP requirements for bid surety bond, state licensure and appeals process for a breach of contract actions are not expected to have an impact on Medicare beneficiaries.

d. Alternatives Considered

Section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, provides that a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, and (2) provided proof of having obtained the bid surety bond for each CBA associated with its bid(s) in a form specified by the Secretary. No alternatives to this bid surety bond requirement were considered. However, while we are proposing that the bid surety bond be in an amount of $100,000, we are seeking comments on whether a lower bond amount for a certain subset of bidding entities, for example, small suppliers as defined by 42 CFR 414.402, would be appropriate. Additionally, we are seeking comments on the impact of the bid surety bond requirement on participation in the DMEPOS CBP. No alternatives were considered for the state licensure requirement, as § 414.414(b)(3) of the regulations already requires suppliers to have state and local licensure.

For appeals for breach of contract actions, we believe that it would be beneficial to expand the appeals process to any of the breach of contract actions that CMS may take pursuant to § 414.422(g)(2). The alternative is to retain the current appeals process for terminations, while still allowing suppliers to appeal other breach of contract actions through an undefined process. However, in order to provide an opportunity for notice and comment, we believe that the better option is to revise the current regulations to allow for a clear and defined appeals process for any breach of contract action that CMS may take.

5. DMEPOS Provisions

a. Effects of the Methodology for Adjusting DMEPOS Fee Schedule Amounts for Similar Items With Different Features Using Information From the DMEPOS Competitive Bidding Programs

We estimate that our proposal for a methodology for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from the DMEPOS CBPs will generate small savings by lowering the price of similar items to be equal to the weighted average of the SPAs for the items based on the item weights assigned under competitive bidding. The reduced price causes lower copayments to the beneficiary. We believe our proposal would also prevent beneficiaries from potentially receiving lower cost items at higher coinsurance rates. Suppliers will be impacted little by the methodological change because the proposal has a small saving attached to it.

b. Effects of the Proposal for Determining Single Payment Amounts for Similar Items With Different Features Under the DMEPOS Competitive Bidding Program

We estimate that our proposal for a methodology for determining single payment amounts for certain groupings of similar items with different features under the DMEPOS CBPs will generate small savings by not allowing SPAs for similar items without features to be priced higher than items with features. Our proposal would benefit beneficiaries who would have lower coinsurance payments as a result of this proposal. We believe our proposal would also prevent beneficiaries from potentially receiving lower cost items at higher coinsurance rates. Suppliers will have a reduced administrative burden due to the fact that bidding is simplified.

c. Effects of the Proposed Revision to the Bid Limits Under the DMEPOS Competitive Bidding Program

We estimate our proposed revision to the bid limits for items under the DMEPOS CBP will not have a significant fiscal impact on the Medicare program because we anticipate little change in Medicare payment due to the revised bid limits. This revision will provide clearer limits. We estimate our proposed revision to the bid limits at the unadjusted fee level would have little fiscal impact in that competitions will continue to reduce prices. This proposed rule would benefit suppliers and beneficiaries because payments would be allowed to fluctuate somewhat to account for increases in the costs of furnishing items, including newer technology items.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 33 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various[17] provisions of this proposed rule.

TABLE 33—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS and AKI for CY 2017	
Annualized Monetized Transfers	$50 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments	$ 10 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2019[17]	
Category	Transfers
Annualized Monetized Transfers	−$15.5 million
Category	Costs
Annualized Monetized ESRD Provider Costs	$21 thousand.
ESRD QIP for PY 2020	
Category	Transfers
Annualized Monetized Transfers	−$22 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$91 million.

DME Provisions

Category	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	−$1.9 −$1.9	2016 2016	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers.		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	−$7.5 −$7.8	2016 2016	7% 3%
From Whom to Whom	Federal government to Medicare providers.		

XVII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

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[17] We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The values presented here capture those previously finalized impacts plus the collection of information requirements related for PY 2018 presented in this notice of proposed rulemaking.

Approximately 15 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 15 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 32. Using the definitions in this ownership category, we consider the 568 facilities that are independent and the 354 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.7 percent increase in payments for CY 2017. An independent facility (as defined by ownership type) is also estimated to receive a 0.4 percent increase in payments for CY 2017.

We are unable to estimate whether patients will go to ESRD facilities for AKI dialysis, however, we have estimated there is a potential for $2.0 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities. As a result, this proposed rule is not estimated to have a significant impact on small entities.

We estimate that of the 2,840 ESRD facilities expected to receive a payment reduction in the PY 2020 ESRD QIP, 349 are ESRD small entity facilities. We present these findings in Table 21 ("Estimated Distribution of PY 2020 ESRD QIP Payment Reductions") and Table 23 ("Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2020") above. We estimate that the payment reductions will average approximately $11,510 per facility across the 2,840 facilities receiving a payment reduction, and $13,884 for each small entity facility. Using our estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total estimated payment reductions for 922 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 922 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.49 percent in PY 2020.

We anticipate that the bid surety bond provision will have an impact on all suppliers, including small suppliers; therefore, we are requesting comments regarding the bid bond amount. The state licensure and appeal of preclusion proposed rules are not expected to have an impact on any supplier.

We expect our proposals for a methodology for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from the DMEPOS CBPs, our proposed change for submitting bids for a grouping of two or more similar items with different features, our proposal for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and our proposed revision to the bid limits for items under the DMEPOS CBP will not have a significant impact on a substantial number of small suppliers. Although suppliers furnishing items and services outside CBAs do not have to compete and be awarded contracts in order to continue furnishing these items and services, the fee schedule amounts for these items and services will be more equitable using the proposals established as a result of this rule. We believe that these rules will have a positive impact on suppliers because it reduces the burden and time it takes for suppliers to submit bids and data entry. It will also allow for suppliers to furnish items necessary to beneficiaries while getting compensated a reasonable payment.

Therefore, the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 139 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 139 rural hospital-based dialysis facilities will experience an estimated 0.1 percent decrease in payments. As a result, this proposed rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

XVIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This proposed rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $141 million.

XIX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XX. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XXI. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and is posted on the CMS Web site at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov*.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 494

Conditions for Coverage for End-Stage Renal Disease Facilities.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; 42 U.S.C. 1395l(a), (i), and (n); 42 U.S.C. 1395x(v); 42 U.S.C. 1395hh; 42 U.S.C. 1395rr; 42 U.S.C. 1395tt; 42 U.S.C. 1395ww; sec. 124 of Pub. L. 106–113, 113 Stat. 1501A–332; sec. 3201 of Pub. L. 112–96, 126 Stat. 156; sec. 632 of Pub. L. 112–240, 126 Stat. 2354; sec. 217 of Pub. L. 113–93, 129 Stat. 1040; sec. 204 of Pub. L. 113–295, 128 Stat. 4010; and sec. 808 of Pub. L. 114–27, 129 Stat. 362.

■ 2. The heading for part 413 is revised to read as set forth above:

■ 3. Section 413.194 is amended by revising paragraph (a)(1) to read as follows:

§ 413.194 Appeals.

(a) * * *

(1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by CMS under § 413.89(h)(3) may request review by the contractor or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

* * * * *

■ 4. Section 413.215 is amended by revising paragraph (b) to read as follows:

§ 413.215 Basis of payment.

* * * * *

(b) In addition to the per-treatment payment amount, as described in § 413.215(a), the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.89(h)(3) of this part.

■ 5. Add Subpart K to part 413 to read as follows:

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

Sec.
413.370 Scope.
413.371 Definition.
413.372 AKI dialysis payment rate.
413.373 Other adjustments to the AKI dialysis payment rate
413.374 Renal dialysis services included in the AKI dialysis payment rate
413.375 Notification of changes in rate-setting methodologies and payment rates.

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

§ 413.370 Scope.

This subpart implements section 1834(r) of the Act by setting forth the principles and authorities under which CMS is authorized to establish a payment amount for renal dialysis services furnished to beneficiaries with an acute kidney injury in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171.

§ 413.371 Definition.

For purposes of the subpart, the following definition applies:

Individual with Acute Kidney Injury. The term individual with acute kidney injury means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

§ 413.372 AKI dialysis payment rate.

The amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for such year under section 1881(b)(14), that is, the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373.

§ 413.373 Other adjustments to the AKI dialysis payment rate.

The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

§ 413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act.

(b) Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in § 413.171, but that are related to their dialysis treatment as a result of their AKI, would be separately payable, that is, drugs, biologicals, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting.

§ 413.375 Notification of changes in rate-setting methodologies and payment rates.

(a) Changes to the methodology for payment for renal dialysis services furnished to beneficiaries with AKI as well as any adjustments to the AKI payment rate other than wage index will be adopted through notice and comment rulemaking.

(b) Annual updates in the AKI dialysis payment rate as described in § 413.372 that do not include those changes described in paragraph (a) are announced by notice published in the **Federal Register** without opportunity for public comment.

(c) Effective for cost reporting periods beginning on or after January 1, 2017, on an annual basis CMS updates the AKI dialysis payment rate.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 7. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 8. Section 414.210 is amended by revising paragraph (g)(6) to read as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(6) *Adjustments of single payment amounts resulting from price inversions under the DMEPOS Competitive Bidding Program.*

(i) In situations where a price inversion defined in § 414.402 occurs under the DMEPOS Competitive Bidding Program in a competitive bidding area (CBA) following a competition for a grouping of similar items identified in paragraph (g)(6)(ii) of this section, prior to adjusting the fee schedule amounts under § 414.210(g) the single payment amount for each item in the grouping of similar items in the CBA is adjusted to be equal to the weighted average of the single payment amounts for the items in the grouping of similar items in the CBA.

(ii) The groupings of similar items subject to this rule include—

(A) Enteral infusion pumps (HCPCS codes B9000 and B9002).

(B) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, and E0304).

(C) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373).

(D) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).

(E) Seat lift mechanisms (HCPCS codes E0627, E0628, and E0629).

(F) TENS devices (HCPCS codes E0720 and E0730).

(G) Walkers (HCPCS codes E0130, E0135, E0141, and E0143).

(iii) The weight for each item (HCPCS code) used in calculating the weighted average described in paragraph (g)(6)(ii) of this section is equal to the proportion of total nationwide allowed services furnished in calendar year 2012 for the item (HCPCS code) in the grouping of similar items, relative to the total nationwide allowed services furnished in calendar year 2012 for each of the other items (HCPCS codes) in the grouping of similar items.

* * * * *

■ 9. Section 414.402 is amended by adding the definitions of "Bidding entity," "Price Inversion," and "Total nationwide allowed service" in alphabetical order to read as follows:

§ 414.402 Definitions.

* * * * *

Bidding entity means the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.

* * * * *

Price inversion means any situation where the following occurs: One item (HCPCS code) in a grouping of similar items (*e.g.,* walkers, enteral infusion pumps, or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (*e.g.,* wheels, alarm, or Group 2 performance); the average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and, following a competition, the SPA for the code with the feature is lower than the SPA for the code without that feature.

* * * * *

Total nationwide allowed services means the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services.

■ 10. Section 414.412 is amended by revising paragraphs (b)(2) and (d) and adding paragraph (h) to read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C, without the application of § 414.210(g), or Subpart D, without the application of § 414.105, or Subpart I of this part. The bids submitted for items in accordance with paragraph (d)(2) of this section cannot exceed the weighted average, weighted by total nationwide allowed services, as defined in § 414.202, of the payment amounts that would otherwise apply to the grouping of similar items under Subpart C, without the application of § 414.210(g), or Subpart D, without the application of § 414.105.

* * * * *

(d) *Separate bids.* (1) Except as provided in paragraph (d)(2) of this section, for each product category that a supplier is seeking to furnish under a Competitive Bidding Program, the supplier must submit a separate bid for each item in that product category.

(2) An exception to paragraph (d)(1) of this section can be made in situations where price inversions defined in § 414.402 have occurred in past competitions for items within groupings of similar items within a product category. In these situations, an alternative method for submitting bids for these combinations of codes may be announced at the time the competition begins. Under this alternative method, the combination of codes for the similar items is the item for bidding purposes, as defined under § 414.402. Suppliers submit bids for the code with the highest total nationwide allowed services for calendar year 2012 (the "lead item") within the grouping of codes for similar items, and the bids for this code are used to calculate the single payment amounts for this code in accordance with § 414.416(b)(1). The bids for this code would also be used to calculate the single payment amounts for the other codes within the grouping of similar items in accordance with § 414.416(b)(3). For subsequent competitions, the lead item is identified as the code with the highest total nationwide allowed services for the most recent and complete calendar year that precedes the competition. The groupings of similar items subject to this rule include—

(i) Enteral infusion pumps (HCPCS codes B9000 and B9002).

(ii) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0266, E0265, E0290, E0291, E0292, E0293, E0294, E0295, E0296, E0297, E0301, E0302, E0303, and E0304).

(iii) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373).

(iv) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, K0823, K0824, K0825, K0826, K0827, K0828, and K0829).

(v) Seat lift mechanisms (HCPCS codes E0627, E0628, and E0629).

(vi) TENS devices (HCPCS codes E0720 and E0730).

(vii) Walkers (HCPCS codes E0130, E0135, E0140, E0141, E0143, E0144, E0147, E0148, and E0149).

* * * * *

(h) *Requiring bid surety bonds for bidding entities.* (1) *Bidding* *requirements.* For competitions beginning on or after January 1, 2017, and no later than January 1, 2019, a bidding entity may not submit a bid(s) for a CBA unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission.

(2) *Bid surety bond requirements.* (i) The bid surety bond issued must include at a minimum:

(A) The name of the bidding entity as the principal/obligor;

(B) The name and National Association of Insurance Commissioners number of the authorized surety;

(C) CMS as the named obligee;

(D) The conditions of the bond;

(E) The CBA covered by the bond;

(F) The bond number;

(G) The date of issuance; and

(H) The bid bond value of $100,000.00.

(ii) The bid surety bond must be maintained until it is either collected upon due to forfeiture or the liability is returned for not meeting bid forfeiture conditions.

(3) *Forfeiture of bid surety bond.* (i) When a bidding entity is offered a contract for a CBA/product category ("competition") and its composite bid for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition and the bidding entity does not accept the contract offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond via Electronic Funds Transfer (EFT) from the respective bonding company. As one bid surety bond is required for each CBA in which the bidding entity is submitting a bid, the failure to accept a contract offer for any product category within the CBA when the entity's bid is at or below the median composite bid rate will result in forfeiture of the bid surety bond for that CBA.

(ii) Where the bid(s) does not meet the specified forfeiture conditions in paragraph (h)(3)(i) of this section, the bid surety bond liability will be returned within 90 days of the public announcement of contract suppliers for the CBA. CMS will notify the bidding entity that it did not meet the specified forfeiture requirements and the bid surety bond will not be collected by CMS.

(4) *Penalties.* (i) A bidding entity that has been determined to have falsified its bid surety bond may be prohibited from participation in the DMEPOS Competitive Bidding Program for the current round of the Competitive Bidding Program in which it submitted a bid and also from participating in the next round of the Competitive Bidding Program. Offending suppliers will also be referred to the Office of Inspector General and Department of Justice for further investigation.

(ii) A bidding entity, whose composite bid is at or below the median composite bid rate, that—

(A) Accepts a contract award and

(B) Is found to be in breach of contract for nonperformance of the contract to avoid forfeiture of the bid surety bond will have its contract terminated and will be precluded from participation in the DMEPOS Competitive Bidding Program.

■ 11. Section 414.414 is amended by revising paragraph (b)(3) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(b) * * *

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids. CMS may not award a contract to any entity in a CBA unless the entity meets applicable State licensure requirements.

* * * * *

■ 12. Section 414.416 is amended by adding a new paragraph (b)(3) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) * * *

(3) In the case of competitions where bids are submitted for an item that is a combination of codes for similar items within a product category as identified under § 414.412(d)(2), the single payment amount for each code within the combination of codes is equal to the single payment amount for the lead item or code with the highest total nationwide allowed services multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (*i.e.*, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the code to the average of the 2015 fee schedule amounts for all areas for the lead item.

■ 13. Section 414.422 is amended by revising paragraph (g) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(g) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions, which will be specified in the notice of breach of contract:

(i) Suspend the contract supplier's contract;

(ii) Terminate the contract;

(iii) Preclude the contract supplier from participating in the competitive bidding program; or

(iv) Avail itself of other remedies allowed by law.

■ 14. Section 414.423 is revised to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contract and where CMS has issued a notice of breach of contract indicating its intent to take action(s) pursuant to § 414.422(g)(2).

(a) *Breach of contract.* CMS may take one or more of the actions specified in § 414.422(g)(2) as a result of a supplier's breach of their DMEPOS Competitive Bidding Program contract.

(b) *Notice of breach of contract.* (1) *CMS notification.* If CMS determines a supplier to be in breach of its contract, it will notify the supplier of the breach of contract in a notice of breach of contract.

(2) *Content of the notice of breach of contract.* The CMS notice of breach of contract will include the following:

(i) The details of the breach of contract.

(ii) The action(s) that CMS is taking as a result of the breach of the contract pursuant to § 414.422(g)(2), and the duration of or timeframe(s) associated with the action(s), if applicable.

(iii) The right to request a hearing by a CBIC hearing officer and, depending on the nature of the breach, the supplier may also be allowed to submit a corrective action plan (CAP) in lieu of requesting a hearing by a CBIC hearing officer, as specified in paragraph (c)(1)(i) of this section.

(iv) The address to which the written request for a hearing must be submitted.

(v) The address to which the CAP must be submitted, if applicable.

(vi) The effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless:

(A) A timely hearing request has been filed; or

(B) A CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

(c) *Corrective action plan (CAP).* (1) *Option for a CAP.* (i) CMS has the option to allow a supplier to submit a written CAP to remedy the deficiencies identified in the notice at its sole discretion, including where CMS determines that the delay in the effective date of the breach of contract action(s) caused by allowing a CAP will not cause harm to beneficiaries. CMS will not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime, or for any other reason determined by CMS.

(ii) If a supplier chooses not to submit a CAP, if CMS determines that a supplier's CAP is insufficient, or if CMS does not allow the supplier the option to submit a CAP, the supplier may request a hearing on the breach of contract action(s).

(2) *Submission of a CAP.* (i) If allowed by CMS, a CAP must be submitted within 30 days from the date on the notice of breach of contract. If the supplier decides not to submit a CAP the supplier may, within 30 days of the date on the notice, request a hearing by a CBIC hearing officer.

(ii) Suppliers will only have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable to CMS or is not properly implemented, suppliers will receive a subsequent notice of breach of contract. The subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to paragraph (1)(i) of this section.

(d) *The purpose of the CAP.* The purpose of the CAP is: (1) For the supplier to remedy all of the deficiencies that were identified in the notice of breach of contract.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS for each applicable breach of contract action concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as identified in the notice of breach of contract.

(2) If CMS accepts the CAP, including the supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement a CAP that was accepted by CMS, or if CMS does not accept the CAP submitted by the supplier, then the supplier will receive a subsequent notice of breach of contract, as specified in paragraph (b) of this section.

(f) *Right to request a hearing by the CBIC Hearing Officer.* (1) A supplier who receives a notice of breach of contract (whether an initial notice of breach of contract or a subsequent notice of breach of contract under § 414.422(e)(3)) has the right to request a hearing before a CBIC hearing officer who was not involved with the original breach of contract determination.

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be received by the CBIC within 30 days from the date of the notice of breach of contract.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, the breach of contract action(s) will take effect 45 days from the date of the notice of breach of contract.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the parties' request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the parties at least 30 days before the date of the hearing.

(4) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days' notice of the change.

(5) The hearing officer's scheduling notice must provide the parties to the hearing the following information:

(i) A description of the hearing procedure.

(ii) The specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract or that the breach of contract action(s) is not appropriate.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the hearing officer.

(v) A notification that all evidence submitted, both from the supplier and CMS, will be provided in preparation for the hearing to all affected parties at least 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof and evidence submission.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the hearing officer with convincing evidence that it has not breached its contract or that the breach of contract action(s) is not appropriate.

(2) The supplier's evidence must be submitted with its request for a hearing.

(3) If the supplier fails to submit the evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the hearing officer within 10 days of receiving the scheduling notice.

(5) The hearing officer will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing at least 15 days prior to the scheduled date of the hearing.

(i) *Role of the Hearing Officer.* The hearing officer will conduct a thorough and independent review of the evidence including the information and documentation submitted for the hearing and other information that the hearing officer considers pertinent for the hearing. The role of the hearing officer includes, at a minimum, the following:

(1) Conduct the hearing and decide the order in which the evidence and the arguments of the parties are presented;

(2) Determine the rules on admissibility of the evidence;

(3) Examine the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties;

(5) Determine the rules for requesting documents and other evidence from other parties;

(6) Ensure a complete record of the hearing is made available to all parties to the hearing;

(7) Prepare a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the hearing officer and considered as part of the hearing; and

(8) Comply with all applicable provisions of 42 U.S.C. Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing officer recommendation.* (1) The hearing officer will issue a written recommendation(s) to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the hearing officer has demonstrated that an extension is needed due to the complexity of the matter or heavy workload. In situations where there is more than one breach of contract action presented at the hearing, the hearing officer will issue separate recommendations for each breach of contract action.

(2) The recommendation(s) will explain the basis and the rationale for the hearing officer's recommendation(s).

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced during the hearing along with its recommendation(s).

(k) *CMS' final determination.* (1) CMS' review of the hearing officer's recommendation(s) will not allow the supplier to submit new information.

(2) After reviewing the hearing officer's recommendation(s), CMS' decision(s) will be made within 30 days from the date of receipt of the hearing officer's recommendation(s). In situations where there is more than one breach of contract action presented at the hearing, and the hearing officer issues multiple recommendations, CMS will render separate decisions for each breach of contract action.

(3) A notice of CMS' decision will be sent to the supplier and the hearing officer. The notice will indicate:

(i) If any breach of contract action(s) included in the notice of breach of contract, specified in paragraph (b)(1) of this section, still apply and will be effectuated, and

(ii) The effective date for any breach of contract action specified in paragraph (k)(3)(i) of this section.

(4) This decision(s) is final and binding.

(l) *Effect of breach of contract action(s).* (1) *Effect of contract suspension.* (i) All locations included in the contract cannot furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items for the duration of the contract suspension.

(ii) The supplier must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items on a recurring basis of the suspension of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice.

(B) The notice to the beneficiary must inform the beneficiary that they must select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(2) *Effect of contract termination.* (i) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

(ii) The supplier must notify all beneficiaries, who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice of termination.

(B) The notice to the beneficiary must inform the beneficiary that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(3) *Effect of preclusion.* A supplier who is precluded will not be allowed to participate in a specific round of the Competitive Bidding Program, which will be identified in the original notice of breach of contract, as specified in paragraph (b)(1) of this section.

(4) *Effect of other remedies allowed by law.* If CMS decides to impose other remedies under § 414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract, as specified in paragraph (b)(2) of this section.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 15. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 16. Amend § 494.1 by revising paragraph (a)(3) and adding paragraph (a)(7) to read as follows:

§ 494.1 Basis and Scope.

(a) * * *

(3) Section 1861(s)(2)(F) of the Act, which describes "medical and other health services" covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B)), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1881(b)(14) to an individual with acute kidney injury (as defined in section 1834(r)(2)).

* * * * *

(7) Section 1861(s)(2)(F) of the Act, which authorizes coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI.

* * * * *

Dated: June 16, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 22, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–15188 Filed 6–24–16; 4:15 pm]

BILLING CODE 4120–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 126 June 30, 2016

Part III

Department of Energy

Federal Energy Regulatory Commission

18 CFR Part 35

Settlement Intervals and Shortage Pricing in Markets Operated by Regional Transmission Organizations and Independent System Operators; Final Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM15–24–000; Order No. 825]

Settlement Intervals and Shortage Pricing in Markets Operated by Regional Transmission Organizations and Independent System Operators

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is revising its regulations to address certain practices that fail to compensate resources at prices that reflect the value of the service resources provide to the system, thereby distorting price signals, and in certain instances, creating a disincentive for resources to respond to dispatch signals. We require that each regional transmission organization and independent system operator align settlement and dispatch intervals by: Settling energy transactions in its real-time markets at the same time interval it dispatches energy; settling operating reserves transactions in its real-time markets at the same time interval it prices operating reserves; and settling intertie transactions in the same time interval it schedules intertie transactions. We also require that each regional transmission organization and independent system operator trigger shortage pricing for any interval in which a shortage of energy or operating reserves is indicated during the pricing of resources for that interval. Adopting these reforms will align prices with resource dispatch instructions and operating needs, providing appropriate incentives for resource performance.

DATES: This rule will become effective September 13, 2016.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Order No. 825

Final Rule

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I. Introduction

1. In this Final Rule, we address certain practices that fail to compensate resources at prices that reflect the value of the service resources provide to the system, thereby distorting price signals, and in certain instances, creating a disincentive for resources to respond to dispatch signals. We require, pursuant to section 206 of the Federal Power Act (FPA),[1] that each regional transmission organization (RTO) and independent system operator (ISO) align settlement and dispatch[2] intervals by: (1) Settling energy transactions in its real-time markets at the same time interval it dispatches energy;

(2) settling operating reserves transactions in its real-time markets at the same time interval it prices operating reserves;[3] and (3) settling intertie transactions[4] in the same time interval it schedules intertie transactions (settlement interval requirements). We also require, pursuant to section 206 of the FPA, that each RTO/ISO establish a mechanism to trigger shortage pricing for any interval in which a shortage of energy or operating reserves is indicated during the pricing of resources for that interval (shortage pricing requirement).

2. Some current RTO/ISO settlement practices fail to reflect the value of providing a given service, thereby distorting price signals and failing to provide appropriate signals for resources to respond to the actual operating needs of the market. One such practice occurs when RTOs/ISOs dispatch resources every five minutes but perform settlements based on an hourly integrated price, or when RTOs/ISOs schedule intertie transactions every fifteen minutes, but perform settlements on an hourly integrated price. This misalignment between dispatch and settlement intervals distorts the price signals sent to resources and fails to reflect the actual value of resources responding to operating needs because compensation will be based on average output and average prices across an hour, rather than output and prices during the periods of greatest need within a particular hour.

3. We also find that a second problem occurs if there is a mismatch between the time when a system experiences a shortage of energy and operating reserves and the time when prices reflect the shortage condition. This can be particularly problematic when, for example, an RTO's/ISO's market rules require a shortage to last a minimum time period before triggering shortage pricing. In this instance, short-term prices fail to reflect system conditions and potential reliability costs, as well as the value of both internal and external market resources responding to a dispatch signal. In addition, inaccurate price signals are provided to market participants if shortage pricing is still in effect after the shortage has been resolved.

4. To address these problems associated with differing dispatch intervals and settlement intervals, as well as with shortage pricing triggers, we are setting forth the settlement interval requirements and the shortage pricing requirement in this Final Rule.[5] These settlement interval and shortage pricing requirements will help ensure that resources have price signals that provide incentives to conform their output to dispatch instructions, and that prices reflect operating needs at each dispatch interval.

5. As set forth in the NOPR, we reiterate the goals of price formation are to: (1) Maximize market surplus for consumer and suppliers; (2) provide correct incentives for market participants to follow commitment and dispatch instructions, make efficient investments in facilities and equipment, and maintain reliability; (3) provide transparency so that market participants understand how prices reflect the actual marginal cost of serving load and the operational constraints of reliably operating the system; and, (4) ensure that all suppliers have an opportunity to recover their costs.[6]

6. As noted in the NOPR, the reforms adopted in this Final Rule advance at least two of the Commission's goals

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[1] 16 U.S.C. 824e (2012).

[2] As mentioned in the Notice of Proposed Rulemaking, the Commission sometimes uses the term "dispatch" as shorthand when describing how RTOs/ISOs acquire and price energy and operating reserves. With respect to operating reserves, the Commission uses dispatch to describe the intervals at which they are acquired and priced. *See Settlement Intervals and Shortage Pricing in Markets Operated by Regional Transmission Organizations and Independent System Operators*, 80 FR 58,393 (Sept. 29, 2015), FERC Stats. & Regs. ¶ 32,710, at P 1 (2015) (NOPR).

[3] Operating reserves refer to certain ancillary services procured in the wholesale market, although they are often defined differently in each RTO/ISO. Operating reserves typically include: (a) Regulating Reserve, used to account for very short-term deviations between supply and demand (*e.g.*, 4 to 6 seconds); (b) Spinning, or Synchronous Reserve, which is capacity held in reserve and synchronized to the grid and able to respond within a relatively short amount of time (*e.g.*, within 10 minutes), to be used in case of a contingency, such as the loss of a generator; and (c) Non-Spinning Reserve, capacity that is not synchronized to the grid and which can take longer to respond (*e.g.*, within 10–30 minutes) in case of a contingency. Federal Energy Regulatory Commission, *Price Formation in Organized Wholesale Electricity Markets: Staff Analysis of Shortage Pricing*, Docket No. AD14–14–000, at 3 n.7 (Oct. 2014), *http://www.ferc.gov/legal/staff-reports/2014/AD14-14-pricing-rto-iso-markets.pdf* (Shortage Pricing Paper).

[4] Intertie transactions are transactions across RTO/ISO borders, including imports, exports and wheel-through transactions.

[5] We are not at this time proposing to change the price paid by any RTO/ISO when shortage pricing is triggered.

[6] *See* Notice Inviting Post-Technical Workshop Comments, Docket No. AD14–14–000, at 1 (Jan. 16, 2015); Notice, Docket No. AD14–14–000 (June 19, 2014).

with respect to price formation. First, the proposed reforms will help provide correct incentives for market participants to follow commitment and dispatch instructions,[7] to make efficient investments in facilities and equipment, and to maintain reliability. Specifically, requiring RTOs/ISOs to align the settlement and dispatch intervals will more accurately reward resources that are providing energy and ancillary services in periods of the greatest need and will discourage provision of energy and ancillary services immediately following periods of system stress. Doing so will enhance the incentive to follow an RTO's/ISO's dispatch signal and thus help maintain system reliability. This reform will also reward resources that can flexibly respond to system needs, thus creating an incentive for resources to make efficient investments in facilities and equipment. Similarly, implementing shortage pricing for any dispatch interval during which a shortage of energy or operating reserves occurs will provide an incentive for resources to ensure that they are available to respond to high prices, which should help alleviate shortages and avoid shortage pricing during subsequent dispatch intervals. This reform would also ensure that resources operating during a shortage are compensated for the value of the service that they provide, regardless of whether the shortage is short-lived.

7. Second, the proposed reforms will also help provide transparency and certainty so that market participants understand how compensation and prices reflect the actual marginal cost of serving load and the operational constraints of reliably operating the system. Requiring settlement intervals to match dispatch intervals will make resource compensation more transparent by, among other things, increasing the proportion of resource payment provided through payments of energy and operating reserves rather than uplift. Further, requiring RTOs/ISOs to trigger shortage pricing for an interval in which a shortage of energy or operating reserves is indicated during the pricing of resources for that interval will ensure that prices transparently reflect the operational constraints of reliably operating the system. This increased transparency, in turn, better informs decisions to build or maintain resources and enhances consumers' ability to hedge. The benefits summarized above and discussed in detail below would ultimately help to ensure just and reasonable rates.

8. As discussed below, we require each RTO/ISO to submit a compliance filing with the tariff changes needed to implement this Final Rule within 120 days of the Final Rule's effective date. We will allow a further 12 months from the compliance filing date for the tariff changes implementing reforms to settlement intervals to be effective, and 120 days from that same compliance filing date for the tariff changes implementing shortage pricing reforms to be effective.[8]

II. Background

9. The Commission has addressed price formation in organized markets on prior occasions. For example, in Order No. 719, the Commission addressed shortage pricing[9] and required RTOs/ISOs to develop and implement shortage pricing rules that would apply during operating reserve shortages to "ensure that the market price for energy reflects the value of energy during an operating reserve shortage."[10] The Commission required such rules out of concern that inappropriate price signals during an operating reserve shortage would provide an insufficient incentive for market participants to take appropriate actions.

10. In June 2014, the Commission initiated a proceeding, in Docket No. AD14–14–000, to evaluate issues regarding price formation in the energy and ancillary services markets operated by RTOs/ISOs (price formation proceeding). In the notice initiating that proceeding, the Commission stated that there may be opportunities for the RTOs/ISOs to improve the energy and ancillary services price formation process. As set forth in the notice, locational marginal prices (LMP) and market-clearing prices used in energy and ancillary services markets ideally "would reflect the true marginal cost of production, taking into account all physical system constraints, and these prices would fully compensate all resources for the variable cost of providing service."[11] Pursuant to the notice, staff conducted outreach and convened technical workshops on the following four general issues: (1) Use of uplift payments; (2) offer price mitigation and offer price caps; (3) scarcity and shortage pricing; and (4) operator actions that affect prices.[12] The Commission also released staff reports on these topics. In one of those reports, issued in October 2014, staff analyzed shortage pricing issues.[13]

11. In its January 2015 Notice Inviting Comments, the Commission requested comments on questions that arose from the price formation technical workshops.[14] In response, among other price formation issues, commenters addressed settlement intervals and shortage pricing.

12. On September 17, 2015, the Commission issued a NOPR proposing to require that each RTO/ISO: (1) Settle energy transactions in its real-time markets at the same time interval it dispatches and prices energy, and settle operating reserves transactions in its real-time markets at the same time interval it prices operating reserves; and (2) trigger shortage pricing for any dispatch interval during which a shortage of energy or operating reserves occurs.[15] The Commission sought comments on these proposals, and sought comment on: (1) Whether settlement interval reforms are appropriate for intertie transactions that are scheduled on intervals different from the intervals on which RTOs/ISOs dispatch internal real-time energy; and (2) whether it is appropriate to align the settlement interval for intertie transactions with external scheduling intervals, *e.g.*, fifteen minutes.[16] Additionally, the Commission sought comment on whether to require that RTOs/ISOs settle real-time operating reserves transactions at the same interval as real-time energy dispatch and settlement intervals or whether a settlement interval that differs from an RTO's/ISO's real-time energy dispatch interval would be appropriate for some operating reserves transactions.[17]

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[7] The Commission notes that the reforms proposed herein would further augment existing mechanisms in each RTO/ISO market that provide incentives to follow dispatch instructions, such as penalties for excessive or deficient energy and the allocation of commitment and dispatch costs to deviations from energy dispatch targets. *See, e.g.,* MISO, FERC Electric Tariff, 40.3.3(a) (36.0.0) (allocating Revenue Sufficiency Guarantee costs to, inter alia, resources providing excessive or deficient energy), 40.3.4 (33.0.0) (charges for excessive or deficient energy deployment).

[8] The Commission has followed a similar approach with the timelines for compliance and implementation in the past. *See, e.g., Frequency Regulation Compensation in the Organized Wholesale Power Markets,* Order No. 755, FERC Stats. & Regs. ¶ 31,324, at P 201 (2011), *reh'g denied,* Order No. 755–A, 138 FERC ¶ 61,123 (2012).

[9] *Wholesale Competition in Regions with Organized Electric Markets,* Order No. 719, FERC Stats. & Regs. ¶ 31,281, at PP 192–194 (2008), *order on reh'g,* Order No. 719–A, FERC Stats. & Regs. ¶ 31,292, *order on reh'g,* Order No. 719–B, 129 FERC ¶ 61,252 (2009).

[10] Order No. 719, FERC Stats. & Regs. ¶ 31,281 at P 194.

[11] Notice, Docket No. AD14–14–000, at 2 (June 19, 2014).

[12] *Id.* at 1, 3–4.

[13] *See* Shortage Pricing Paper.

[14] Notice Inviting Post-Technical Workshop Comments, Docket No. AD14–14–000 (Jan. 16, 2015).

[15] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 14.

[16] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 39.

[17] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 40.

Finally, the Commission sought comment on the implementation schedule and the costs of implementation.[18] A list of commenters and the abbreviated names used for them in this Final Rule appears in the Appendix.

III. Discussion

A. Settlement Interval Reform

1. Need for Reform

13. In the NOPR,[19] the Commission preliminarily found that the current RTO/ISO settlement practice of using hourly integrated prices for real-time settlement and five-minute dispatch instructions may fail to reflect the value of providing a given service, and may contribute to lack of a response to the actual operating needs of those markets. In addition, the Commission stated that the use of hourly integrated prices for real-time settlement may discourage resources from following five-minute dispatch instructions, and may increase the need for uplift payments. Therefore, the Commission preliminarily found that the use of hourly integrated prices for real-time settlement may result in rates that are unjust and unreasonable.

14. Commenters generally agree with the Commission's preliminary finding regarding the settlement interval proposal. For example, EPSA states that "[w]hen real-time settlements for generation or dispatchable demand are calculated based on hourly prices that are the simple average of sub-hourly prices resulting from the actual dispatch, there is a distortion to the real-time price signal impacting both reliability and efficiency." [20] Similarly, Potomac Economics states that the inconsistency between five-minute dispatch instructions and hourly-average price settlement intervals "creates incentives for generators to not follow the dispatch signal or to simply be inflexible by (a) restricting dispatch range (the difference between a generator's minimum dispatch level and maximum dispatch level) or (b) offering a slower dispatch ramp rate." [21] Potomac Economics notes that while MISO makes uplift payments to generators to alleviate these incentive issues, such payments are "an inferior substitute for a true alignment where each generator, importer or exporter would settle based on the actual value of energy corresponding with its production or transactions in each five-minute interval." [22] ELCON asserts that hourly prices do not "reflect system needs and costs, and may result in over or under recovery of costs depending on how the shortage plays out during the hour. When SPP moved to sub-hourly settlements, overall system costs were lower." [23]

15. In some instances, commenters assert that the Commission should not affirm its preliminary finding on the settlement interval proposal. APPA and NRECA assert that Commission approval of any five-minute settlement implementation process should require vetting and approval by the RTOs'/ISOs' stakeholders.[24] Direct Energy asserts that the Commission should solicit further information from the RTOs/ISOs before determining whether or not to direct settlement interval reforms.[25]

16. Based on analysis of the record, we adopt our preliminary findings, and, as described in detail below, conclude that certain RTO/ISO settlement practices are not just and reasonable and are unduly discriminatory and preferential. Accordingly, we direct each RTO/ISO to align its settlement and dispatch intervals by settling energy transactions in its real-time markets at the same time interval it dispatches energy, settling operating reserves transactions in its real-time markets at the same time interval it prices operating reserves, and settling intertie transactions in the same time interval it schedules intertie transactions, as discussed further herein.

2. Settlement Interval Reform for Energy Transactions and Operating Reserves

a. Proposal

i. Energy Transactions

17. In the NOPR, the Commission proposed to require that each RTO/ISO settle energy transactions in its real-time markets at the same time interval it dispatches energy. The Commission preliminarily found the use of hourly integrated prices for real-time settlement may have the unintended effect of distorting price signals, and, in certain instances, contributing to market participants' failing to respond appropriately to operating needs.[26] Specifically, the Commission stated that hourly integrated prices for real-time settlement may: (1) Not accurately reflect the value a resource provides to the system; (2) discourage resources from following dispatch instructions; and (3) cause increased uplift payments. Therefore, the Commission preliminarily found that the use of hourly integrated prices for real-time settlement may result in rates that are unjust and unreasonable.

18. To remedy any potentially unjust and unreasonable rates caused by the use of hourly integrated prices for real-time settlement, the Commission proposed in the NOPR to require that each RTO/ISO settle energy transactions in its real-time markets at the same time interval it dispatches energy.[27]

19. The Commission explained that in the short-term, the settlement interval proposal should improve incentives for resources to respond quickly to dispatch instructions, which should in turn lead to operators taking fewer out-of-market actions to ensure that supply meets demand. The Commission noted that by improving resources' response to dispatch instructions, the settlement interval proposal would result in a more efficient use of generation resources to the benefit of all consumers. In the long-term, the Commission maintained that these reforms should provide more accurate price signals, which should provide, together with other market price signals, the appropriate incentives to build or maintain resources that can respond to energy or operating reserve deficiencies.[28]

20. In addition, the Commission noted, where settlement and dispatch intervals are aligned, resources dispatched economically during high-priced periods would receive those higher prices rather than an hourly average of the dispatch interval LMPs, thereby reducing the need to make uplift payments.

ii. Operating Reserves

21. The Commission proposed requiring that each RTO/ISO "settle operating reserves transactions in its real-time markets at the same time interval it prices operating reserves." [29] Although the Commission noted that dispatch and pricing of energy and operating reserves are closely linked through co-optimization in the real-time market, it also noted that certain RTOs/ISOs acquire operating reserves on a different time interval than they dispatch energy.[30] The Commission sought comment on whether the Commission should require RTOs/ISOs to settle all real-time operating reserves transactions at the same time interval as real-time energy dispatch and

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[18] NOPR, FERC Stats. & Regs. ¶ 32,710 at PP 56, 60.

[19] NOPR, FERC Stats. & Regs. ¶ 32,710 at PP 26–33.

[20] EPSA Comments, Pope Aff. at 2–3.

[21] Potomac Economics Comments at 4.

[22] Potomac Economics Comments at 4–5.

[23] ELCON Comments at 2.

[24] APPA and NRECA Comments at 4.

[25] Direct Energy Comments at 6.

[26] NOPR, FERC Stats. & Regs. ¶ 32,710 at PP 26–33.

[27] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 34.

[28] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 35.

[29] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 34.

[30] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 40.

settlement intervals, or whether a settlement interval that differs from an RTO's/ISO's real-time energy dispatch interval would be appropriate for some operating reserves transactions.[31]

b. Current Practices in the RTOs/ISOs

i. Energy Transactions

22. The following table describes how each RTO/ISO currently dispatches and settles real-time energy transactions:

TABLE 1—RTO/ISO DISPATCH AND SETTLEMENT INTERVALS FOR ENERGY

	Real-time dispatch [32] (minutes)	Real-time settlement [33]
CAISO	5	5 minute.
ISO–NE	5	hourly average.
MISO	5	hourly average.
NYISO	5	5 minute.
PJM	5	hourly average.
SPP	5	5 minute.

ii. Operating Reserves

23. The RTOs/ISOs vary in how they settle and treat operating reserves. For example, CAISO represents that it settles its operating reserve transactions on fifteen-minute intervals and dispatches energy on five-minute intervals.[34] MISO states that it currently calculates settlements for real-time operating reserves transactions at the same interval that they are dispatched, *i.e.*, five minutes, but that actual settlements are on an hourly basis due to the specific calculations MISO makes.

24. The PJM Market Monitor explains that the synchronized and regulation reserves markets in PJM clear hourly but already incorporate five-minute LMP data for calculating opportunity costs. The PJM Market Monitor states that the offer price in PJM's synchronized reserve market includes both the direct short-run marginal cost of providing synchronized reserves, which does not vary every five minutes, and the opportunity cost of providing synchronized reserves, which does vary with five-minute LMPs. The PJM Market Monitor explains that PJM currently updates the opportunity cost every five minutes using five-minute LMP data for the Tier 2 synchronized reserve market and recalculates the market clearing price every five minutes, with settlement based on the average of the five-minute clearing price.[35]

25. The PJM Market Monitor explains that, in PJM's regulation market, the offer price includes both the direct short-run marginal cost of providing regulation, which does not vary every five minutes, and the opportunity cost of providing regulation, which varies with five-minute LMPs. The PJM Market Monitor adds that PJM currently updates the opportunity cost every five minutes using five-minute LMP data for the regulation market and recalculates the clearing price every five minutes, with settlement based on the average of five-minute clearing prices. The PJM Market Monitor also notes that PJM purchases other forms of operating reserves on a cost basis, including Tier 1 synchronized reserves, non-synchronized reserves, and day-ahead scheduling reserves.[36]

26. NYISO explains that it uses five-minute intervals to settle its real-time markets for energy, regulation service, and operating reserves.[37] ISO–NE currently has hourly integrated settlement for its real-time energy transactions and its real-time operating reserves. However, ISO–NE states it intends to implement five-minute settlement of real-time operating reserves in connection with implementing five-minute settlement of real-time energy transactions, which is a current discussion among ISO–NE stakeholders.[38] SPP prices and settles operating reserve products in its real-time market on a dispatch interval, or five minute, basis.[39]

c. Comments on the Proposed Settlement Interval Reform

27. Twenty-seven of the thirty commenters providing input on this issue generally support the NOPR's proposed settlement interval reform.[40] As described below, many assert that the proposed reform will align the price signals with system conditions and provide accurate incentives for generation units to follow dispatch instructions.[41] Others point to additional benefits.

i. Comments From the RTOs/ISOs

28. The ISO/RTO Council supports the Commission's goals of aligning prices with resource dispatch instructions and operating needs and specifically supports the settlement interval proposal for energy transactions. The ISO/RTO Council states that the proposed settlement interval reform will make resource compensation more transparent by increasing the proportion of payments to resources through the price paid for energy as opposed to uplift.[42]

29. In separate comments, NYISO, ISO–NE., MISO, and PJM support the settlement interval proposal for both energy and operating reserve transactions. Likewise, in separate comments, CAISO supports the settlement interval proposal for energy transactions, but does not support requiring RTOs/ISOs to settle all real-time operating reserves transactions at the same interval as real-time energy dispatch and settlement intervals.

30. CAISO states that the settlement interval proposal would improve market efficiency, and that accurate price signals provide market participants with incentives to develop needed capabilities and to offer those capabilities into the market.[43] CAISO states that where settlement and dispatch intervals are aligned, resources dispatched economically during high-priced periods should receive high prices, thus reducing the need to pay uplift caused by non-alignment of settlement and dispatch intervals.[44]

31. However, CAISO does not support requiring RTOs/ISOs to settle all real-time operating reserves transactions at the same interval as real-time energy dispatch and settlement intervals.

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[31] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 40.

[32] *See* CAISO, eTariff, 34.5 (17.0.0); ISO–NE., Transmission, Markets and Services Tariff, Market Rule 1, III.2.3 (15.0.0); MISO, FERC Electric Tariff, 40.2 (34.0.0); NYISO Markets and Services Tariff, 4.4.2.1 (17.0.0); PJM OATT, Attachment K, Appendix, 2.3 (2.0.0); SPP, OATT, Sixth Revised Volume No. 1, Attachment AE, 6.2.2 (1.0.0).

[33] *See* CAISO, eTariff, 11.5 (2.0.0), Appendix A, Settlement Interval (2.0.0); ISO–NE., Transmission, Markets and Services Tariff, Market Rule 1, III.2.2(b) (15.0.0); MISO, FERC Electric Tariff, 40.3 (32.0.0), 40.3.1 (32.0.0), 40.3.3 (36.0.0); NYISO, NYISO Tariffs, NYISO Markets and Services Tariff, 4.4.2.1, 4.4.2.8 (17.0.0); PJM, Intra-PJM Tariffs, OATT, Attachment K, Appendix, 2.5(e), (4.0.0), 3.2.1(e), (f) (28.0.0); SPP, OATT, Sixth Revised Volume No. 1, Attachment AE, 8.6, 8.6.1 (2.1.0). The above tariff citations refer to internal transactions. CAISO settles its intertie interchange transactions on fifteen-minute intervals. *See* CAISO, eTariff, HASP Block Intertie Schedule (0.0.0).

[34] CAISO Comments at 8.

[35] PJM Market Monitor Comments at 8.

[36] PJM Market Monitor Comments at 8.

[37] NYISO Comments at 2–3.

[38] ISO–NE Comments at 2–3.

[39] SPP Market Protocols, Sections 4.5.4 and 4.5.9.

[40] Ameren Comments at 1, 3–4; ANGA Comments at 2–5; CAISO Comments at 2; CEA Comments at 3–6; Dominion Comments at 1–2; DTE Comments at 3–4; EDP Renewables Comments at 2; EEI Comments at 2; ESA Comments at 2–4; Entergy Nuclear Power Marketing Comments at 2; EPSA Comments at 1–5; Exelon Comments at 4; Financial Marketers Coalition Comments at 1; Golden Spread Initial Comments at 1–3; Inertia Power and DC Energy Comments at 2; ISO–NE Comments at 1; MISO Comments at 2, 9; NEI Comments at 1; NGSA Comments at 2–5; ODEC Comments at 3; PJM Power Providers Comments at 2–5; Potomac Economics Comments at 2; Powerex Comments at 6; PSEG Comments at 3; Public Interest Organizations Comments at 5; SPP Market Monitor Comments at 2; Westar Comments at 1.

[41] Inertia Power and DC Energy Comments at 2; Potomac Economics Comments at 1; Westar Comments at 1; PSEG Comments at 3.

[42] ISO/RTO Council Comments at 2.

[43] CAISO Comments at 7.

[44] CAISO Comments at 7.

Instead, CAISO asserts that it is appropriate to maintain its current fifteen-minute procurement and settlement interval for operating reserves transactions, which differs from the five-minute real-time energy dispatch interval. CAISO explains that its current settlement methodology aligns ancillary services commitment with internal generation commitment and intertie transactions scheduling so that the market accurately reflects the overall amount of supply resources available to provide energy and ancillary services.[45]

32. NYISO supports the settlement interval proposal and asserts that its use of five-minute intervals to settle its real-time markets for energy, regulation service, and operating reserves, has provided significant incentives for resources to follow dispatch instructions and opportunities for supply resources to obtain full payment for their performance based on actual system conditions.[46]

33. ISO–NE contends that settling on sub-hourly or five-minute intervals would help to improve price signals and resource compensation.[47] ISO–NE states that five-minute settlements will help improve price formation by ensuring that compensation for real-time performance sends more accurate market signals of power system conditions when energy is provided.[48] ISO–NE supports the settlement interval proposal for operating reserve transactions. It asserts that settling all real-time operating reserves transactions at the same interval as real-time energy dispatch and settlement intervals would assist in aligning dispatch following incentives in markets that simultaneously co-optimize energy and reserve dispatch in real-time. ISO–NE states it intends to implement five-minute settlement of real-time operating reserves in connection with implementing five-minute settlement of real-time energy transactions, which is a current discussion among ISO–NE stakeholders.[49]

34. MISO asserts that the inconsistency between dispatch and settlements may produce financial outcomes that do not align with the guiding principles of co-optimized (energy and ancillary services) security constrained economic dispatch.[50] If the Commission requires five-minute settlements of operating reserves, MISO states that it would modify its operating reserves settlements from its current hourly method of settling operating reserves to align with real-time energy transactions.[51]

35. PJM states that ancillary services, including operating reserves, should settle on the same interval as energy because they are co-optimized. PJM argues that not doing so could yield discrepancies between the prices used to settle each product and could therefore undo enhancements made since implementation of Order No. 719, reduce market efficiencies, disrupt operations, and hinder proper price formation.[52] PJM states that it intends to change its market rules to settle energy and ancillary services transactions in its real-time energy market at the same interval on which it dispatches resources.[53]

ii. Comments by Market Monitors

36. The PJM Market Monitor agrees that it would be appropriate to implement five-minute pricing for the reasons stated in the NOPR, and that implementing five-minute settlements will contribute significantly to reducing uplift payments in PJM, an ongoing goal in the PJM region.[54] The PJM Market Monitor states that, while it is appropriate to include the impact of five-minute LMP changes on the cost of operating reserves in the form of synchronized reserves and regulation, the PJM design for these markets currently incorporates those impacts. The PJM Market Monitor asserts that no additional changes to PJM market and non-market mechanisms for acquiring operating reserves are currently necessary to incorporate changes in five-minute LMPs.[55]

37. Potomac Economics, which serves as the market monitor for ISO–NE., MISO, and NYISO, argues that hourly settlements encourage resources not to follow dispatch instructions or to decrease their flexibility by restricting dispatch ranges and offering slower ramp rates, and states that MISO pays uplift to alleviate these issues. Potomac Economics cites its 2014 MISO State of the Market Report to show how five-minute settlements would change total payments to resources compared to current hourly settlements. This analysis showed that fossil-fueled resources in 2014 received settlements that were $35 million less than they would have received if the settlement were based on five-minute prices and output, and that only one-fifth of this lost value was paid via uplift. In contrast, Potomac Economics represents that non-fossil resources were paid on net in hourly revenues slightly above what they would have received with five-minute settlements. Potomac Economics asserts that five-minute settlement provides greater compensation to fossil resources, more accurately representing the flexibility fossil resources provide to the system. In contrast, Potomac Economics argues that hourly settlement overvalues wind resources because such resources cannot ramp up in response to higher prices, are negatively correlated with load and contribute to higher congestion at higher output levels.[56] Potomac Economics states that the settlement interval proposal will provide incentives for better resource performance, will improve price signals, and will improve markets' short-run commitment and dispatch of existing resources.[57]

38. The SPP Market Monitor agrees with the Commission's preliminary finding that aligning settlement and dispatch intervals would make resource compensation more transparent by increasing the proportion of resource payments made through energy and operating reserve payments instead of uplift.[58] The SPP Market Monitor states that aligning dispatch and settlement intervals in neighboring markets would enhance price signals at seams and enhance market efficiency.[59]

iii. Comments Supporting the Proposed Settlement Interval Reform

39. Many commenters expressly support the NOPR's settlement interval proposal, citing many of the benefits that were outlined in the NOPR.[60] They generally argue that the settlement interval proposal will provide incentives for generators to follow dispatch more precisely, thus leading to

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[45] CAISO Comments at 17–18.

[46] NYISO Comments at 2–3.

[47] ISO–NE Comments at 2.

[48] ISO–NE Comments at 2.

[49] ISO–NE Comments at 2–3.

[50] MISO Comments at 2.

[51] MISO Comments at 7–8.

[52] PJM Comments at 9.

[53] PJM Comments at 2.

[54] PJM Market Monitor Comments at 2, 4.

[55] PJM Market Monitor Comments at 8–9.

[56] Potomac Economics Comments at 6.

[57] Potomac Economics Comments at 1.

[58] SPP Market Monitor Comments at 2.

[59] SPP Market Monitor Comments at 2–3.

[60] Ameren Comments at 1, 3–4; ANGA Comments at 2–5; CAISO Comments at 2; CEA Comments at 3–6; Dominion Comments at 1–2; DTE Comments at 3–4; EDP Renewables Comments at 2; EEI Comments at 2; ESA Comments at 2–4; Entergy Nuclear Power Marketing Comments at 2; EPSA Comments at 1–5; Exelon Comments at 4; Financial Marketers Coalition Comments at 1; Golden Spread Initial Comments at 1–3; Inertia Power and DC Energy Comments at 2; ISO–NE Comments at 1; MISO Comments at 2, 9; NEI Comments at 1; NGSA Comments at 2–5; PJM Power Providers Comments at 2–5; Potomac Economics Comments at 2; Powerex Comments at 6; PSEG Comments at 3; Public Interest Organizations Comments at 5; SPP Market Monitor Comments at 2; Westar Comments at 1; AEMA Comments at 2; XO Energy Comments at 1; PJM Market Monitor at 2; ODEC at 3.

better resource performance, and improved reliability.[61] They also assert that the settlement interval proposal will properly compensate resources for the service they provide and will more fully recognize the value of flexible or fast-ramping resources.[62] In addition, they generally state that the settlement interval proposal will lead to fewer out-of-market payments, will increase transparency, and will support more efficient market outcomes.[63]

40. More specifically, Exelon asserts that the settlement interval proposal will support ongoing market improvements, such as ISO–NE's performance incentive mechanism, effective in June 2018, that will pay resources bonuses or impose penalties based on performance during operating reserve shortages that last five minutes or longer. Exelon argues that ISO–NE's market must settle at five-minute intervals to implement this mechanism completely.[64]

41. According to EDP Renewables, greater participation of fast ramping renewable resources will also enhance resource adequacy, produce cost savings for consumers, and improve grid resilience.[65]

42. Some commenters also argue that the settlement interval proposal will reduce market inefficiencies and lead to greater investment. PSEG asserts that the proposed reforms correct market flaws that have caused inefficiencies in both price signals and resource dispatch decisions.[66] ELCON states that the proposed settlement reform addresses an embedded inconsistency in market operation that promotes gaming and other forms of ill behavior or inefficiencies.[67] EDP Renewables argues that the proposed reforms will also yield savings, remove opportunities for market manipulation, and encourage investment in new services and new technologies, all of which will result in a more robust and resilient grid and help both consumers and suppliers through more efficient market operation.[68]

43. EPSA argues that implementing sub-hourly settlement intervals is needed to obtain the full benefits of other price formation reforms to improve the accuracy with which real-time prices communicate the time-dependent and location-dependent value of incremental energy and ancillary services.[69]

44. TAPS does not oppose the settlement interval proposal, as long as it does not impose an undue burden on load serving entities.[70]

45. EPSA supports the settlement interval proposal for operating reserves. It argues that real-time operating reserves should be co-optimized in the dispatch and settled with energy for every hourly sub-interval (generally five minutes) to ensure that resources are compensated for following RTO/ISO instructions and are indifferent to providing either energy or operating reserves during periods of high energy or operating reserves prices.[71] EPSA emphasizes the importance of sending sub-hourly price signals to ensure that operating reserves are available in sub-hourly intervals due to their contribution to maintaining reliability, further stating that sub-hourly settlements for operating reserves send information to the market relating to the potential profitability of incremental investments to enhance the sub-hourly availability of such reserves.[72] EPSA argues that to ensure accurate prices for both energy and operating reserves, RTOs/ISOs should be required to co-optimize these products in real-time because suppliers should be indifferent to providing incremental energy and operating reserves in each sub-hourly interval to allow the RTO/ISO to perform a reliable least-cost dispatch.[73]

46. Dominion supports the settlement interval proposal for operating reserves. However, Dominion argues that only specific reserve products should settle at the same interval that they are priced and that other types of settlement provisions, such as make-whole payments, should not.[74] Dominion explains that, in PJM, for example, "balancing Operating Reserves" includes the costs to dispatch resources out-of-merit for reliability or to cover deficiencies in the day-ahead market solution.[75] According to Dominion, these resources do not provide a specific reserve product; rather, these resources are made whole when they are dispatched to address a mismatch between day-ahead commitment and real-time requirements. Dominion therefore requests that the Commission not require the settlement intervals for these types of operating reserve to change.[76]

47. PSEG supports applying the proposed settlement intervals to both real-time energy transactions and real-time operating reserves. PSEG explains that given the linkage between energy transactions and reserve services, settling those products on different intervals would introduce dislocations, and incent resource actions that could disrupt these co-optimization objectives, essentially undermining the Commission's objectives in the NOPR.[77]

48. The New Jersey Board concurs with the PJM Market Monitor that no changes should be made in PJM's synchronized reserve and regulation markets given that the opportunity cost component in these ancillary services markets, which is the only cost component subject to five-minute changes in LMP, already accounts for the five-minute interval changes.[78] Duke acknowledges potential benefits from aligning operating reserve transactions with their respective settlement intervals but argues that stakeholders should consider whether operating reserves transactions should be aligned with settlement intervals for energy given the costs of doing so.[79] Although it takes no position on the operating reserves proposal, EEI states that additional clarity from the Commission on the definition of operating reserve transactions would be helpful, given the varied definitions of reserve products among regions. EEI states that such regional variation warrants further consideration.[80]

iv. Comments Opposed to the Proposed Settlement Interval Reform

49. Several commenters oppose the settlement interval proposal. Direct Energy states that the Commission should solicit information from RTOs/ISOs to determine whether existing generation resources are able to respond effectively to five-minute price signals before determining whether any settlement interval reform is warranted.[81] Direct Energy doubts the ability of longer lead-time resources to respond to five-minute price signals

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[61] Inertia Power and DC Energy Comments at 2; Westar Comments at 1, 3; EEI Comments at 6–7; Exelon Comments at 4–5.

[62] Public Interest Organizations Comments at 2–3; ELCON Comments at 2–3; EDP Renewables Comments at 2–3; ESA Comments at 3; NEI Comments at 14.

[63] *See* supra note 60; ELCON Comments at 3; Exelon Comments at 4–5.

[64] Exelon Comments at 5.

[65] EDP Renewables Comments at 3.

[66] PSEG Comments at 3.

[67] Public Interest Organizations Comments at 2–3; ELCON Comments at 2–3.

[68] EDP Renewables Comments at 2.

[69] EPSA Comments at 6–7, Pope Aff. at 4–5.

[70] TAPS Comments at 4.

[71] EPSA Comments, Pope Aff. at 11.

[72] EPSA Comments, Pope Aff. at 11.

[73] EPSA Comments, Pope Aff. at 12–13.

[74] Dominion Comments at 3.

[75] Dominion Comments at 3.

[76] Dominion Comments at 3.

[77] PSEG Comments at 4–5.

[78] New Jersey Board Comments at 4.

[79] Duke Comments at 5.

[80] EEI Comments at 9–10 & n.16.

[81] Direct Energy Comments at 6.

during periods of extreme price volatility, and surmises that look-ahead unit commitment and dispatch software results could exacerbate swings in generation and load balance. Direct Energy states that a high-priced dispatch interval could encourage dispatch of peaking generation, which would take several minutes with longer ramp times and cause other resources to ramp up more quickly. Direct Energy argues that this could lead to an oversupply and to depressed prices, thus making the longer-ramping resources responding to the original signal uneconomic by running below their costs and incurring uplift—the opposite of the goal of the settlement interval proposal.[82]

50. Duke, APPA and NRECA, and Concerned Cooperatives argue that the Commission should refrain from requiring a one-size-fits-all approach.[83] Duke, APPA and NRECA, and Concerned Cooperatives contend that RTO/ISO stakeholder processes should vet this issue and consider issues such as the costs, benefits, types of changes needed to implement this reform, price formation issues more generally, and unintended consequences.[84] Duke states that this approach would notify the Commission with regard to possible solutions, cost of implementation, and the timeframe in which the RTO/ISO could reasonably address each issue.[85] Additionally, Concerned Cooperatives disagree with the Commission's conclusion that reforming the settlement intervals will result in more efficient use of generating resources.

51. Concerned Cooperatives argue that the benefits of moving to five-minute settlements will not offset the cost. They state that the Potomac Economics report cited in the NOPR shows that switching to matching intervals would force MISO market participants to expend millions of dollars on upgrades and operation and maintenance (O&M) costs, without realizing lower rates. Instead, those participants would face an annual increase of approximately $28 million, after netting the estimated $6.6 million system benefit from the increased payments to generators of about $35 million dollars.[86]

52. Concerned Cooperatives further argue that the Commission relies solely upon a letter filed in Docket No. AD14–14–000[87] to support its finding with no analysis as to whether the observed increase in capacity factors for internal combustion engines in SPP was the result of SPP's adoption of five-minute settlement intervals or other factors.[88] Concerned Cooperatives argue that, even if there was some marginal benefit to the settlement interval proposal, many market participants would not benefit from the reform even though they would be responsible for funding it.[89] Concerned Cooperatives represent that 90 to 95 percent of their transactions take place in the day-ahead market, which settles on an hourly basis, and that adopting five-minute settlement intervals in the real-time market does not help Concerned Cooperatives hedge prices.[90] Concerned Cooperatives also state that the National Renewable Energy Laboratory study cited in the NOPR in support of adopting five-minute settlement intervals also recognizes that limiting market complexity may be a reason to maintain hourly settlements, and that RTOs/ISOs already have tools to encourage resources to follow efficient schedules, such as uninstructed deviation penalties and *ex post* pricing rules. Concerned Cooperatives recommend that the Commission instead identify objectives and allow RTOs/ISOs to pursue options for achieving those objectives.[91]

d. Commission Determination

i. Energy Transactions

53. We adopt the NOPR proposal to require that each RTO/ISO settle energy transactions in its real-time markets at the same time interval it dispatches energy, as discussed below.[92] We find that the settlement interval requirement for energy transactions will meet the Commission's price formation goals by more accurately reflecting the value of the service a resource provides to the system, which, in so doing, helps to ensure that rates are just and reasonable and not unduly discriminatory or preferential.

54. As discussed below, providing the correct incentives for market participants to follow commitment and dispatch instructions, make efficient investments in facilities and equipment, maintain reliability, and increase transparency is fundamental to proper formation of energy prices, helping to ensure just and reasonable rates, terms and conditions of service.

55. One important element of ensuring reliable grid operations is resources following dispatch instructions. The requirement that each RTO/ISO settle energy transactions at the same interval it dispatches energy sends accurate market signals of power system conditions, thus encouraging resources to follow commitment and dispatch instructions, a point noted by ISO–NE.[93]

56. The settlement interval requirement for energy transactions also provides an incentive to make efficient investments in facilities and equipment.[94] In the long-term, we expect that appropriate compensation would help to encourage efficient investments in facilities and equipment, enabling reliable service. We also find that the settlement interval requirement will provide incentives to more flexible resources, thus leading to more efficient markets, as noted by several commenters.[95] More flexible resources will help system operators address transient system conditions. We find that greater participation of these more flexible resources should generally enhance resource adequacy because it allows the participation of diverse resources and improves reliability, as noted by EDP Renewables.[96]

57. The settlement interval requirement for energy transactions should help in maintaining reliability because resources will have a greater incentive to follow dispatch instructions, as noted by Exelon.[97] In addition, these reforms will provide resource owners with a greater incentive to adequately maintain their equipment, conduct maintenance during non-peak periods, and invest in new and upgraded equipment. As noted by CAISO, linking prices with compensation will pay resources for providing needed flexibility to the market operator and would motivate these resources to improve their operational performance.[98]

58. The settlement interval requirement for energy transactions also results in more accurate market prices, reducing the need for out-of-market operator actions. Under an hourly

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[82] Direct Energy Comments at 3–5.

[83] Duke Comments at 2–3; APPA and NRECA Comments at 4–5; Concerned Cooperatives Comments at 4–5.

[84] Duke Comments at 4; APPA and NRECA Comments at 3; Concerned Cooperatives Comments at 1.

[85] Duke Comments at 4–5.

[86] Concerned Cooperatives Comments at 10 (citing Potomac Economics, 2014 State of the Market Report for the MISO Electricity Markets, at 43–44, Figure 19 (2015)).

[87] Concerned Cooperatives Comments at 11 (citing Comments of Wärtsilä North America, Inc., Docket No. AD14–14–000, at 1–2 (Mar. 6, 2015)).

[88] Concerned Cooperatives Comments at 11.

[89] Concerned Cooperatives Comments at 11.

[90] Concerned Cooperatives Comments at 11.

[91] Concerned Cooperatives Comments at 12.

[92] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 34.

[93] ISO–NE Comments at 2.

[94] EPSA Comments, Pope Aff. at 4.

[95] Public Interest Organizations Comments at 2–3; ELCON Comments at 2–3; EDP Renewables Comments at 2–3; ESA Comments at 3; NEI Comments at 14.

[96] EDP Renewables Comments at 2–3.

[97] Exelon Comments at 4–5.

[98] CAISO Comments at 7.

settlement system, resources do not have the same incentive to follow five-minute prices since compensation is based on an hourly average. Therefore, system operators are more likely to take out-of-market actions in real-time, such as increasing the use of regulating reserves or committing additional resources, to ensure that adequate resources are available to meet system needs. Such actions may result in uplift. By providing incentives to follow dispatch instructions, the settlement interval requirement should reduce such operator actions and, thereby, reduce uplift.[99] When this occurs, energy prices are based on more observable market fundamentals—such as the marginal cost of serving load and the operational constraints of reliably operating the system—and not on less observable operator action.[100] As a result of a reduction in out-of-market uplift payments, resources will perceive stronger financial incentives to perform, especially during stressed system conditions, when the performance of all resources is paramount. Further, we note, this increased transparency, in turn, better informs decisions to build or maintain resources.

59. Taken together, the benefits we expect as a result of this settlement reform will ensure that rates are just and reasonable and not unduly discriminatory or preferential.

60. We are not persuaded by the arguments opposing the settlement interval proposal. Underlying much of the opposition is the assumption that many resources cannot take advantage of five-minute settlement intervals because they are not flexible enough to respond to five-minute dispatch. For example, Direct Energy argues that RTOs/ISOs should report the types of resources able to effectively modify their output to respond to five-minute price signals.[101] The concern Direct Energy identifies is, in fact, one of the objectives of this reform. Specifically, resources that are not able to respond quickly enough to address acute system needs should not receive the same level of compensation as those resources that are able to flexibly respond.[102] Further, we note that all RTOs/ISOs have a combination of resources, some of which can respond within five minutes and some that cannot, and that knowing the exact percentages of resources available to respond to prices is not determinative of whether the reforms adopted here will prove beneficial. Instead, we believe it is important to ensure settlement practices do not distort existing five-minute pricing signals.

61. We are not persuaded by Concerned Cooperatives' argument that the settlement interval proposal should be rejected because market participants, such as Concerned Cooperatives, funding the reform do not have a large fraction of their positions in the real-time market and therefore will not benefit significantly from it.[103] We find that aligning prices and settlement intervals will enhance the operation of markets by ensuring resources respond to actual system condition regardless of the percentage of resources that clear in the day-ahead market.

62. We also disagree with Concerned Cooperatives' statement that the Commission relied upon a single document to support its finding without additional analysis.[104] Commenters supporting the reform have provided sound economic analysis and examples demonstrating the value of the proposed settlement reform.[105] Though Concerned Cooperatives state that many market participants would not benefit from the reform even though they would be responsible for funding it,[106] we believe that many market participants are likely to benefit from the reform through improved economic incentives to respond to system needs. Potomac Economics' analysis of fossil-fueled and non-fossil-fueled resources[107] demonstrates that settlement reform will incentivize generator flexibility, improve generators' dispatch performance, and increase investments in more flexible resources.

63. Concerned Cooperatives express concern that adopting five-minute settlement intervals could result in errors and disputes that could lead to resettlement and uncertainty for the market.[108] All RTOs/ISOs currently compute five-minute LMPs. Therefore, there is no new data being generated or calculated that would lead to additional need for resettlement or increased uncertainty. Concerned Cooperatives have cited neither examples of more errors and disputes on RTO/ISO systems currently using five-minute settlement intervals, nor examples of additional resettlement and uncertainty for the market. Also, we find that, while administratively-determined uninstructed deviation penalties (which Concerned Cooperatives suggest could be used in lieu of settlement reform) are appropriate in certain contexts, settlements based on the actual value of energy corresponding with its production or transaction in each five-minute interval provide more accurate incentives for resources to respond to price signals.

64. Concerned Cooperatives also assert that the objective of incenting market participants to follow dispatch instructions or invest in upgrades must be considered in the context of existing market rules that already may provide incentives for investment in faster ramping capability.[109] To the extent an RTO/ISO has a functional mechanism to encourage the installation of fast-ramping resources, this Final Rule will augment the existing RTO/ISO mechanisms.

65. Contrary to Concerned Cooperatives' argument, we are not persuaded to abandon the settlement interval proposal because a Potomac Economics report indicates that it would have resulted in an additional $28 million in increased energy costs on the MISO system in 2014.[110] First, we recognize that that there could be higher revenues to generators, but we believe that this is the correct reflection of value provided in these circumstances and would send an improved signal for long-term investment and short-term performance, to the overall benefit of the market. Second, it is important to note that the Potomac Economics report indicates that for many settlement intervals during 2014, MISO resources were paid an hourly settlement rate lower than what five-minute settlements would justify. Thus, the Potomac

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[99] Reducing out-of-market uplift payments can be beneficial to RTOs'/ISOs' market participants because, among other reasons, charges to market participants for uplift are often volatile. As a result, market participants may build risk premiums into their resource bids in the real-time energy market to shield them from the uncertainty associated with unexpected uplift charges. *See* Staff Analysis of Uplift in RTO and ISO Markets, Docket No. AD14–14–000, at 18 (Aug. 2014), *http://www.ferc.gov/legal/staff-reports/2014/08-13-14-uplift.pdf*. In addition, making system conditions and compensation more transparent through market prices will make that price apparent to all available resources and thus encourage them to fully participate in the market, which is likely to reduce generation costs incurred by load.

[100] In addition to greater transparency, reducing uplift is a goal generally. For example, "[t]he implementation of five minute settlements would contribute significantly to the reduction of uplift payments, which is an ongoing goal of PJM, of the Market Monitor and of PJM members." PJM Market Monitor Comments at 4.

[101] Direct Energy Comments at 6.

[102] This rule does not require resources to be dispatched more quickly than they are now, but it does increase the incentive for those resources that can and do respond quickly.

[103] Concerned Cooperatives Comments at 11.

[104] Concerned Cooperatives Comments at 11.

[105] EPSA Comments, Pope Aff. at 2–14; Potomac Economics Comments at 3–7; *See also supra* note 60.

[106] Concerned Cooperatives Comments at 11.

[107] Potomac Economics Comments at 5–6.

[108] Concerned Cooperatives Comments at 12.

[109] Concerned Cooperatives Comments at 6.

[110] Concerned Cooperatives Comments at 10.

Economics report should be viewed as indicating a need to correct settlement practices, rather than indicating a windfall to resources. Third, it is not clear that the proposal will result in generally increased energy payments to generators. For example, an ISO–NE study for the year 2013 found that the net increase in real-time energy credits on its system (once the decrease in real-time reserve credits was considered) would have been only $600,000.[111] Finally, due to the increased efficiencies resulting from improving incentives to respond to market price signals, total costs to electric wholesale customers over time are likely to decrease.

66. Additionally, some commenters argue that other types of settlement provisions, such as make-whole payments, should not be subject to settlement interval reform. We would like to clarify that the Final Rule does not apply to make-whole payments for units dispatched out-of-merit.

67. We disagree with the recommendation of some commenters that the decision to modify settlement intervals should be subject to a stakeholder process.[112] RTOs/ISOs implementing this Final Rule are free to use a stakeholder process within the implementation timelines specified herein, but we see no need to further delay this reform. This does not limit stakeholders' input as RTOs/ISOs form their compliance filings in response to this aspect of the Final Rule.

68. We conclude that the settlement interval requirement for energy transactions should ensure that hourly settlement practices do not distort five-minute price signals in RTOs/ISOs. Instead, the compensation provided to resources must reflect the value of a resource providing given services to ensure appropriate economic incentives to meet system needs.

ii. Operating Reserves

69. We adopt the proposal in the NOPR that RTOs/ISOs settle real-time operating reserves transactions at the same time interval that they price operating reserves. This requirement for operating reserves will accomplish the Commission's price formation goals and thereby ensure just and reasonable rates, and will further preserve the co-optimization of operating reserves with energy. Under the settlement interval requirement for operating reserves, to the extent that an RTO/ISO prices operating reserves transactions at a different time interval than it prices internal real-time energy transactions, that RTO/ISO need only settle operating reserves transactions at the same time interval that they are priced. Thus, we will not require an RTO/ISO to settle operating reserves transactions on the same time interval as it settles energy transactions. This will preserve the existing energy and operating reserves co-optimization methodologies of the various RTOs/ISOs.

70. The settlement interval requirement increases transparency and provides the correct incentives to maintain reliability. It also meets the Commission's other price formation goals of encouraging resources to follow the RTO's/ISO's commitment and dispatch instructions and to make efficient investments. The reform to the settlement interval for operating reserves will increase reliability because resource owners will have a greater incentive to adequately maintain their equipment, conduct maintenance during non-peak periods, and invest in new and upgraded equipment. Similar to energy settlement intervals, requiring settlement intervals of operating reserves transactions to match the intervals upon which those reserves are priced will reduce the need for payments made through uplift, make resource compensation more transparent and help ensure that there are adequate operating reserves to maintain reliability. Finally, co-optimized energy and reserve prices are designed so that a resource is indifferent between providing energy or operating reserves. Ensuring that energy and operating reserve settlements are done on the same basis will preserve this indifference and create an incentive for a resource to provide the service the RTO/ISO has instructed it to provide. The reform to operating reserve settlements will, by achieving the Commission's price formation goals and preserving the co-optimization of energy and operating reserves, ensure that rates are just and reasonable.

71. While, as discussed above, some commenters also support RTOs/ISOs settling all real-time operating reserves transactions at the same time interval that they dispatch real-time energy,[113] we are not requiring that these settlement intervals align. CAISO, in defending its current practices, states that it procures operating reserves and settles them on a fifteen-minute basis and distinguishes this type of ancillary service from five-minute real-time energy dispatch.[114] However, CAISO, along with all of the other RTOs/ISOs, supports the requirement that they settle operating reserves transactions at the same time interval that they price these transactions, which accommodates both RTOs/ISOs that currently settle co-optimized reserve transactions on a five-minute basis and those that currently settle these transactions on a fifteen-minute basis. Accordingly, we clarify that CAISO's understanding in this regard is consistent with how operating reserves and energy on its system are "priced," as contemplated by the wording of the settlement interval regulations adopted by this Final Rule.

72. NYISO states that, although it uses sub-hourly settlements in its real-time market, in certain cases, the Commission has approved NYISO performing settlements on an hourly basis, and NYISO argues it should not be required to bring those settlements into alignment with its normal dispatch intervals.[115] NYISO cites limited energy storage resources as an example of services that currently settle hourly and yet follow dispatch instructions and provide resource response in real-time. To the extent NYISO or other RTOs/ISOs seek to argue on compliance that their existing market rules are consistent with or superior to the Final Rule reforms adopted herein, the Commission will entertain those at that time.[116]

73. Although generally supporting the settlement interval requirement for operating reserves, some commenters question whether such a requirement should apply to all reserve products or assert that regional variations should be considered.[117] We appreciate that regional variations may exist among the many different reserve products in the RTOs/ISOs and we clarify that all operating reserve products that have a market-based price are subject to the settlement interval reform.

3. Interties

a. Commission Request for Comments

74. The Commission sought comment on whether the proposed reforms are appropriate for intertie transactions scheduled on intervals different from

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[111] ISO–NE., *Subhourly Real-Time Market Settlements*, A11 ISO Presentation 05–07–14 Revision 1, Matt Brewster, at 11 (May 8, 2014), *http://www.iso-ne.com/committees/key-projects/subhourly-real-time-settlement.*

[112] APPA and NRECA Comments at 4.

[113] PSEG Comments at 4–5; EPSA Comments, Pope Aff. at 11–13.

[114] CAISO Comments at 17–18.

[115] NYISO Comments at 3–4.

[116] *See, e.g., Demand Response Compensation in Organized Wholesale Energy Markets*, Order No. 745, FERC Stats. & Regs. ¶ 31,322, at P 4 & n.7, *order on reh'g and clarification*, Order No. 745–A, 137 FERC ¶ 61,215 (2011), *reh'g denied*, Order No. 745–B, 138 FERC ¶ 61,148 (2012), *vacated sub nom. Elec. Power Supply Ass'n* v. *FERC*, 753 F.3d 216 (D.C. Cir. 2014), *rev'd & remanded sub nom. FERC* v. *Elec. Power Supply Ass'n*, 136 S. Ct. 760 (2016).

[117] *See, e.g.*, Dominion Comments at 3; EEI Comments at 10.

the intervals on which RTOs/ISOs dispatch internal real-time energy.[118]

i. Comments by RTOs/ISOs

75. The ISO/RTO Council asserts that aligning dispatch and pricing should also apply to intertie transactions, adding that this would prevent price discrepancies and may reduce uplift.[119]

76. PJM asserts that intertie transactions should be included in the scope of the Final Rule, noting that it plans to settle intertie transactions on a five-minute basis, consistent with its proposal for its real-time energy market. PJM suggests that, where a transaction is curtailed or the MW quantity is reduced during a fifteen-minute interval due to a reliability directive, each five-minute interval in the transaction should settle on the integrated transaction MW quantity that flowed during the five-minute interval.[120]

77. ISO–NE argues that external interties should settle no less often than the intervals for which they are scheduled. ISO–NE represents that its proposals to implement sub-hourly settlements would fully meet this objective at all its external interfaces.[121] NYISO argues that intertie and internal transactions should have the same settlement interval because this alignment will promote competition, identify the most economic supply option, provide equal incentives to respond to the same operating conditions, and improve the efficiency of interregional transactions.[122]

78. CAISO notes that it already schedules and settles intertie transactions and internal resources on a fifteen-minute basis.[123] However, CAISO also provides three options for scheduling imports and exports on an hourly basis: (1) Economic-bid hourly block; (2) economic-bid hourly block with a single intra-hour schedule change that will be dispatched to zero within the hour if a fifteen-minute price is less than an import's bid price or greater than an export's bid price; and (3) self-scheduled hourly.[124] CAISO requests that the Commission state that CAISO's current market design with granular dispatch and settlement of its real-time energy market is consistent with the settlement interval proposal.[125]

79. CAISO asserts that a blanket requirement that hourly intertie schedules revert to hourly pricing, as was previously the case under its prior market design, would result in the same adverse market outcomes it resolved through its fifteen-minute market enhancement.[126] CAISO requests that the Commission clarify that the availability of hourly block intertie bidding options would not violate the settlement interval proposal because its current market design ensures all internal and external transactions are cleared and settled based on fifteen-minute market intervals that optimize all transactions in its markets.[127]

ii. Comments by Market Monitors

80. The PJM Market Monitor asserts that intertie transactions in PJM cannot be measured accurately enough to support five-minute settlements, noting that accurate measurement is difficult because of differences between actual and scheduled flows. The PJM Market Monitor thus recommends that settlements be based on the same fifteen-minute interval used for external scheduling intervals. The PJM Market Monitor asserts that this approach would more accurately reflect LMP during the actual time period of the transaction and would make the period and settlement of the transaction consistent.[128]

81. The PJM Market Monitor states that alternative settlement approaches include using the integrated price over the same fifteen-minute interval used in scheduling and using five-minute interval settlements.[129]

iii. Comments in Support of Applying Settlement Reform to Interties

82. The New Jersey Board, EEI, EPSA, Dominion, and EDP Renewables concur with the PJM Market Monitor that intertie settlements should be at fifteen-minute intervals, the same interval as external scheduling.[130]

83. Golden Spread states that alignment between dispatch and settlement intervals is generally desirable for the reasons listed in the NOPR, and notes that it believes SPP already aligns dispatch and settlement intervals for intertie transactions on a five-minute basis.[131]

84. ANGA, PSEG, and the Financial Marketers Coalition assert that the logic underlying the proposed settlement reform as applied to internal transactions should apply equally to intertie transactions, and ANGA recommends that the Commission consider evolving these interfaces to five-minute dispatch and settlement, perhaps over the next three to five years.[132]

85. Although it generally agrees that the settlement interval proposal should apply equally to internal and intertie transactions, Financial Marketers Coalition states that, in CAISO, clearing some transactions (such as load and generation) on a five-minute price and others (such as internal and intertie convergence bids) on a fifteen-minute price has yielded price divergence instead of convergence.

iv. Comments Opposed To Applying Settlement Reform to Interties

86. Inertia Power and DC Energy argue that intertie economic dispatch intervals cannot easily be aligned with internal real-time energy dispatch but emphasize the importance of maintaining the highest possible consistency across the seams to ensure a more efficient, resilient, and reliable electrical system.[133]

87. Duke states that the issue of whether to apply the settlement interval proposal to intertie transactions should be discussed in the RTO/ISO stakeholder processes and that they should be treated comparably to reforms to internal transactions.[134]

b. Commission Determination

88. Based upon the comments received on this issue, we modify the regulatory text proposed in the NOPR to require each RTO/ISO to settle intertie transactions in the same time interval that it schedules intertie transactions. The settlement interval requirement for intertie transactions will facilitate the coordination of the scheduling and settlement of intertie transactions, and will discourage inefficient practices such as the chasing of inaccurate intertie prices. For example, if there are very high prices in the first fifteen minutes of an hour, resources will know that for that entire operating hour, there will be a high integrated hourly price. This provides an incentive for resources to increase the volume of intertie transactions for the remainder of the hour, even if the price for the subsequent fifteen-minute interval is much lower reflecting that it may no

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[118] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 39.

[119] ISO/RTO Council Comments at 2.

[120] PJM Comments at 8.

[121] ISO–NE Comments at 2.

[122] NYISO Comments at 5.

[123] CAISO Comments at 12.

[124] CAISO Comments at 9.

[125] CAISO Comments at 10.

[126] CAISO Comments at 14.

[127] CAISO Comments at 15.

[128] PJM Market Monitor Comments at 7.

[129] The PJM Market Monitor in its comments provides examples of these alternatives. PJM Market Monitor Comments at 5–7.

[130] New Jersey Board Comments at 3–4; EEI Comments at 9; EPSA Comments, Pope Aff. at 9; Dominion Comments at 4; EDP Renewables Comments at 5.

[131] Golden Spread Initial Comments at 2.

[132] ANGA Comments at 3–4; Financial Marketers Coalition Comments at 3–4; PSEG Comments at 5.

[133] Inertia Power and DC Energy Comments at 4–5.

[134] Duke Comments at 5.

longer be efficient to schedule such intertie transactions. Most commenters, as described above, agree that such a requirement will aid in the achievement of these goals.

89. However, a difference of opinion exists between PJM and the PJM Market Monitor. PJM supports moving to a five-minute settlement interval for intertie transactions while the PJM Market Monitor supports aligning the settlement interval for intertie transactions with the fifteen-minute scheduling interval for these transactions.

90. If an RTO/ISO settles or proposes to settle intertie transactions using a shorter time interval than by which it schedules such transactions, the RTO/ISO may propose to do so in its compliance filing and demonstrate that such a proposal is consistent with or superior to the Commission's intertie reforms. The compliance filing proceeding will provide a forum in which to consider alternative practices and resolve disputes that may arise within regions, as well as provide for the development of a more complete record on these issues.

91. We decline to clarify for CAISO that the availability of hourly block intertie bidding options would not violate the settlement interval requirement for interties. Such a determination is more appropriately made upon reviewing CAISO's compliance filing and CAISO should justify its proposed treatment for intertie transactions there.

4. Demand Response Resources

a. Comments

92. Several commenters discuss the application of the settlement interval proposal to demand response resources even though the Commission did not specifically solicit those comments and did not make a separate proposal concerning demand response resources apart from other resources considered in the NOPR.

93. The PJM Market Monitor, with the New Jersey Board concurring, recommends that five-minute pricing in energy markets explicitly cover all resources providing energy, including demand side and storage resources.[135] PJM Market Monitor recommends that the Commission require any associated, necessary metering associated with applying the requirement to demand resources.[136]

94. Public Interest Organizations also urge the Commission to make clear that its proposed reforms apply to all resources able to participate in wholesale energy markets.[137] PSEG similarly supports the application of the settlement interval proposal to demand response resources. PSEG states that real-time settlements for demand response resources, or any other load-side resources that are price responsive in wholesale markets, should be based on five-minute intervals, in the same manner as the supply resources with which it competes.[138] PSEG acknowledges that some demand resources will lack necessary meters and/or communication, and states that it would be reasonable to allow these resources a transition period to install them without delaying overall implementation.[139]

95. AEMA states that it recommends that demand response resources have the option to continue to settle on the basis of one-hour meter readings. AEMA asserts that demand resources use hourly intervals because only hourly interval metering may be available and even new advanced metering infrastructure is only capable of fifteen minute interval data, whereas settling on five-minute intervals could entail adding an expense that is an economic barrier to entry for some resources.[140]

96. AEMA also states that few demand response resources have the operational communications to modify their demand at frequent intervals and that frequent demand changes would require more robust communications than may be economic.[141] AEMA further states that the Net Benefits Price Threshold that many RTOs/ISOs established in response to FERC Order No. 745 is applied on an hourly basis and that the industry has universally adopted hourly baseline methodologies for demand response resources.[142]

97. AEMA explains that much of the current energy-related demand response participation relies on the commitment to dispatch for one or more hours and if the bid-offer is accepted for demand response resources, those resources are eligible for uplift payments if the energy prices fall below their bid-offer during their committed dispatch time. AEMA requests that these bid offer guarantees continue to be incorporated in the Final Rule.[143]

b. Commission Determination

98. In using the term "resource" in the NOPR, the Commission intended for the settlement interval proposal to apply to all supply resources, including demand response resources. We find that, as with other resources, aligning the price signal and dispatch signal provides demand response resources capable of following a given dispatch signal the incentive to do so, resulting in a more efficient use of demand response resources in the real-time energy and operating reserve markets. As stated above, all RTOs/ISOs have a combination of resources, some of which can respond within five minutes and some that cannot, and that includes demand response resources. It is important to provide a price signal to all resources, regardless of type or capability, as this will provide proper compensation to those resources capable of responding to five-minute dispatch signals, and will incentivize such capability to those resources that do not currently have it.

99. In response to concerns about the need to upgrade metering technology for demand response resources, we note that this Final Rule does not contemplate requiring any new metering capability, such as five-minute revenue quality metering, and that such metering is not necessary for implementation given RTOs'/ISOs' ability to create five-minute load and generation profiles using telemetry and hourly revenue quality data. We also do not require any changes to baseline methodologies. Although a more granular baseline may provide additional value, RTOs/ISOs need not change their baseline methodology to comply with this Final Rule. Finally, we find that AEMA's arguments regarding the Net Benefits Price Threshold[144] and "make whole" rules are beyond the scope of this Final Rule because it does not require any changes to the Net Benefits Price Threshold or make-whole payments. Even if modest changes to these provisions were required for RTOs/ISOs to comply with this Final Rule, the benefits of this rule would justify such modifications.

5. Load

a. Comments

100. A number of commenters state the proposed rule did not specify whether the settlement interval proposal would apply to load,[145] or, in other

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[135] PJM Market Monitor Comments at 2; New Jersey Board Comments at 2.

[136] PJM Market Monitor Comments at 2; New Jersey Board Comments at 2.

[137] Public Interest Organizations at 5.

[138] PSEG Comments at 5.

[139] PSEG Comments at 5.

[140] AEMA Comments at 4.

[141] AEMA Comments at 4.

[142] AEMA Comments at 3–5 (citing Order No. 745, FERC Stats. & Regs. ¶ 31,322).

[143] AEMA Comments at 5.

[144] AEMA Comments at 3.

[145] For purposes of this Final Rule, the term "load" generally refers to consumption of electricity in the wholesale markets, but not to demand

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words, whether it would change how load is settled and measured.

101. EEI, PSEG, SCE, AEMA, EPSA and CAISO recommend that the Commission not apply the settlement reform to load.[146] The primary arguments these commenters cite against applying the settlement interval proposal to load include: (1) The benefit of settling load on an interval basis is not likely to outweigh the cost, which may include the need for new expensive metering;[147] (2) settlement reform alone will not encourage price responsive load without corresponding changes to state-jurisdictional retail rate design;[148] and (3) because load is not dispatchable, there is no dispatch interval that aligns with load.[149] Direct Energy recommends either not applying the settlement reform to load or delaying implementation until the majority of load has the ability, incentive and information necessary to respond to five-minute settlements.[150] EEI specifically requests that the Commission clarify that it is not proposing to change how load is metered.[151]

102. PJM, however, states that it is advantageous to apply the proposed rule to load, and proposes to settle load on the same interval as dispatch intervals by using a combination of state-estimator and telemetry data for each settlement interval.[152] PJM states that it thus does not foresee changes being required for market participants' metering.[153]

103. Mr. Centolella states that advancing load settlements to reflect the actual interval demand of each load serving entity's customers could remove an important barrier to developing the next generation of responsive demand. Mr. Centolella also encourages the Commission to work with states to optimize collecting customer data, and to evaluate how to support efficient price formation related to the load data used in wholesale settlements.[154]

b. Commission Determination

104. We clarify that the Commission did not propose to apply the settlement interval proposal to load. We also clarify that adoption of the settlement interval requirements are not intended to change how load is metered. The Commission's basis for requiring changes to the settlement interval focused exclusively on supply resources rather than load. As a result, we have no record to require any changes to the settlement interval for load. However, we are not prohibiting settling load on a five-minute basis, and will evaluate any such proposals on a case-by-case basis in separate proceedings submitted pursuant to section 205 of the FPA.

B. Shortage Pricing Reform

1. Need for Reform

105. In the NOPR, the Commission stated that shortage prices send a short-term price signal to provide an incentive for the performance of existing resources and help to maintain reliability. The Commission noted that some RTOs/ISOs currently restrict the use of shortage pricing to certain causes of shortages, or some RTOs/ISOs require a shortage to exist for a minimum amount of time before triggering shortage pricing.[155] The Commission further noted that not invoking shortage pricing when there is a shortage (regardless of the duration or cause of that shortage) distorts price signals that are designed to elicit increased supply and to compensate resources for the value of the services they provide when the system needs energy or operating reserves. Because these price signals fail to reflect adequately the value that a resource provides to the system, the Commission preliminarily found in the NOPR that the resulting price is not just and reasonable.[156]

106. The Commission also noted that its rationale regarding shortage pricing was similar to the rationale the Commission relied on in Order No. 719, in which the Commission determined that "rules that do not allow for prices to rise sufficiently during an operating reserve shortage to allow supply to meet demand are unjust, unreasonable, and may be unduly discriminatory" and that such rules "may not produce prices that accurately reflect the value of energy."[157]

107. Commenters generally support the rationale provided by the Commission in support of the need for reform. For example, as discussed below, MISO, NYISO and ISO–NE all support the need for reform, and CAISO supports the conceptual need, but requests further clarifications. EEI and EPSA also support the Commission's shortage pricing proposal. Conversely, SPP and PJM, in joint comments, oppose implementing shortage pricing in all dispatch intervals, and request revisions if the Commission adopts its proposed reforms.

108. Based on analysis of the record, we adopt our preliminary findings and conclude that existing shortage pricing triggers that do not invoke shortage pricing when there is a shortage (regardless of duration or cause) are unjust and unreasonable and are unduly discriminatory and preferential. Thus, there is a need to reform the use of shortage pricing in RTO/ISO markets, as discussed further herein.

2. NOPR Proposal

109. In order to remedy the potentially unjust and unreasonable rates caused by restrictions on shortage pricing, the Commission proposed to require that RTOs/ISOs institute mechanisms that trigger shortage pricing for any dispatch interval during which a shortage of energy or operating reserves occurs.

3. Comments on the Proposed Shortage Pricing Reform

a. Comments by RTOs/ISOs

110. MISO states that it supports shortage pricing reform and maintains that MISO's current practices are already consistent with the Commission's proposal. Specifically, MISO states its operating reserve demand curve is used in the five-minute dispatch interval and triggers shortage pricing in any five-minute interval in which operating reserve requirements cannot be fully satisfied, regardless of duration or causation.[158] MISO also states that its recent implementation of extended locational marginal pricing (ELMP) considers offline fast-start resources in its price setting algorithm to more accurately reflect the cost of the next MW to meet demand during scarcity conditions.[159] MISO notes that if no economic offline fast-start resources are eligible, it will rely upon the operating reserve demand curve values for shortage pricing. MISO states that it is already compliant with the proposed rule on shortage pricing.[160]

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response acting as a supply resource in the wholesale markets.

[146] EEI Comments at 8–9; PSEG Comments at 5–6; SCE Comments at 2; AEMA Comments at 4–5; EPSA Comments, Pope Aff. at 6–7; CAISO Comments at 16–17.

[147] SCE Comments at 2.

[148] SCE Comments at 2.

[149] CAISO Comments at 16–17.

[150] Direct Energy Comments at 7. *See also* Supplemental Comments of Direct Energy (filed Mar. 4, 2016).

[151] EEI Comments at 8–9.

[152] PJM Comments at 5.

[153] PJM Comments at 5.

[154] Mr. Centolella Comments at 4–6.

[155] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 46.

[156] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 47.

[157] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 48 (citing Order No. 719, FERC Stats. & Regs. ¶ 31,281 at P 192).

[158] MISO Comments at 10.

[159] *See* MISO, Extended Locational Marginal Pricing, Docket No. ER12–668–000 (filed Dec. 22, 2011).

[160] MISO Comments at 11–12.

111. ISO–NE supports the shortage pricing proposal and asserts that its current market rules and real-time pricing systems already comply with the proposed requirement.[161]

112. NYISO supports the shortage pricing proposal, and states that it uses demand curves to price all reserve shortages, regardless of their duration. NYISO adds that it currently implements shortage pricing in its day-ahead and real-time markets using various demand curves for operating reserves, regulating reserves, and transmission security, where the demand curves represent the escalating value of each product as the level of any shortage increases.[162] NYISO also states that it does not interpret the NOPR to be addressing the use of offline resources in real-time pricing or to be implying that practices, such as the NYISO's "Hybrid Pricing" rules,[163] are inconsistent with the NOPR.[164]

113. CAISO agrees with the concept behind the shortage pricing reform and supports its implementation, subject to certain clarifications. CAISO expects that its existing tariff provisions implementing scarcity pricing for energy and ancillary services already comply with the NOPR's proposal. CAISO explains that, in any fifteen-minute interval of the fifteen-minute market, it will co-optimize the procurement of energy and ancillary services based on submitted supply bids and the forecast of demand and its ancillary services requirements. CAISO further explains that, in any given fifteen-minute interval, if effective supply bids are insufficient to clear forecasted demand, scarcity pricing will trigger and thereby indicate a shortage of supply for that applicable fifteen-minute interval. CAISO states that, similarly, if ancillary services bids are not sufficient to meet the ancillary services procurement target, ancillary services scarcity pricing will trigger for that interval.[165]

114. CAISO notes that within a fifteen-minute operating interval it may need to deploy operating reserves to address a contingency in the case of operating reserves, or in the case of regulation to continuously balance supply and demand. CAISO states that it is important that the Final Rule clarify that the deployment of operating reserves or regulation does not necessarily mean a shortage exists. CAISO notes that in some cases the deployment of reserves is made through alternative deployment mechanisms and not in the co-optimization function of the market.[166] CAISO also explains that in any given fifteen-minute market interval, if a shortage is observed, shortage pricing will trigger within that interval and CAISO will not wait for the shortage to materialize beyond that interval before triggering shortage pricing. However, CAISO states that not all price signals triggered by "transient shortages" provide incentives to resources that have the capability to respond to brief-duration shortages.[167]

115. PJM and SPP filed joint comments opposing triggering shortage pricing in any dispatch interval in which a shortage of energy or operating reserves occurs. First, PJM and SPP state that they support shortage pricing only when "a shortage of a particular product exists that presents reliability concerns." [168] PJM and SPP argue that applying shortage prices to shortage events that do not cause reliability concerns allows price increases even when such events are transitory, do not pose reliability concerns, and cannot be addressed due to limitations on resource response. PJM and SPP maintain that applying shortage pricing to some transient shortages will give inaccurate prices and could potentially degrade system reliability, and may also result in market pricing and operations that are contrary to the Commission's stated goals.[169]

116. PJM and SPP further state that they have in place rules related to this issue consistent with the principles and goals of shortage pricing. PJM and SPP urge the Commission to provide flexibility by allowing RTOs/ISOs to implement shortage pricing in the context of their regional rules. This, PJM and SPP assert, will ensure that inefficient pricing does not result.[170]

117. PJM and SPP argue that allowing transient periods of shortage to trigger shortage pricing could overstate the severity of the operating condition and result in prices that do not accurately reflect operating conditions on the system, or last long enough to allow market participants responding to them to take meaningful action. In fact, PJM and SPP assert that responses may occur after the relevant interval has passed, which could be counterproductive operationally and economically. PJM and SPP pose two examples to illustrate this point. As the first example, they posit: PJM carrying the required amount of reserves when a market seller of a generation resource lowers the resource's economic maximum capability, for a brief time (ten minutes or less), causing PJM to have less reserves than its requirement. Currently, PJM can recover these reserves by re-executing its dispatch engine and re-dispatching its system; but under the shortage pricing reform, this could invoke shortage pricing, which would then attract more suppliers than needed and create disincentives for resources to back down once the event was over. In another example, they posit: PJM has scheduled a resource with a ten-minute start-up time to come online to provide energy so that another resource may be reduced to provide reserves; but if the resource scheduled to come online actually takes twenty minutes instead of ten, shortage pricing would be triggered under the shortage pricing proposal, and the second resource, instead of having its output reduced to provide reserves would now need to continue to provide energy, thus potentially leaving PJM short on reserves for a brief period.[171]

118. PJM and SPP introduce another hypothetical scenario from the SPP region. PJM and SPP state that SPP can temporarily use operating reserves to meet energy requirements during transient periods when system conditions do not present reliability concerns. PJM and SPP argue that while this may technically compromise the operating reserve requirement, the condition is transient and is recovered in less than ten minutes. According to PJM and SPP, this is not an operating reserve shortage, but rather a transient reallocation of capacity to manage temporary energy needs caused by the operational characteristics of resources. PJM and SPP further state that the examples described above do not present emergency conditions or

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[161] ISO–NE Comments at 3.

[162] NYISO Comments at 6.

[163] NYISO's Hybrid Pricing rules were adopted in 2001. *See New York Indep. Sys. Operator, Inc.*, 95 FERC ¶ 61,121 (2001). The Hybrid Pricing rules apply to Real-Time Market pricing and relax the minimum operating limits of certain fast-start, block-loaded resources in order to permit them to be eligible to set price based on the incremental need that required their commitment.

[164] NYISO Comments at 7.

[165] CAISO Comments at 20.

[166] CAISO explains that during each fifteen-minute interval in which the resources are deployed, the system is not actually short of supply bids when the operating reserves for that interval are procured. Also, CAISO states that once the reserves are deployed, to the extent that the market allows for full recovery of the required reserves, the contingency event itself does not trigger scarcity pricing for ancillary services. According to CAISO, this is because no actual shortage of operating reserves exists unless there are insufficient resources to meet operational needs for operating reserves in the next applicable fifteen-minute market interval. CAISO Comments at 21–22.

[167] CAISO Comments at 23.

[168] PJM and SPP Comments at 1.

[169] PJM and SPP Comments at 1–2.

[170] PJM and SPP Comments at 2–3.

[171] PJM and SPP Comments at 4.

reliability concerns that would justify shortage pricing.[172]

119. In order to "recognize and respect the fact that not all instances of shortages justify shortage pricing," PJM and SPP propose alternative language for any Final Rule on shortage pricing:

> Each RTO/ISO must establish tariff provisions that implement shortage pricing for pre-defined operating conditions related to a shortage of energy or operating reserves. The Commission will allow each RTO/ISO to develop those provisions based on their regional circumstances, provided that the rules are consistent with shortage pricing principles and are designed to facilitate the goals of this [Final Rule]. The Commission expects that each RTO/ISO will explain why their provisions, or why their current rules, comply with this rule.[173]

120. PJM and SPP further assert that a universal shortage pricing rule requiring shortage pricing even for transient circumstances would require the implementation of operating reserve demand curves that distinguish prices relative to varying degrees of shortage. PJM and SPP explain further that in PJM's case, the current operating reserve demand curves are a step function, which would need to be changed, and in SPP's case it would likely consider the implementation of a pricing gradient demand curve based on different degrees of shortages and their impact on reliability, rather than steep step curves.[174]

b. Comments by Market Monitors

121. Potomac Economics explains that all the markets that it monitors (ISO–NE, NYISO, and MISO) are designed to price all shortages, regardless of duration.[175] Potomac Economics states that it strongly supports the shortage pricing reform and argues that pricing all shortages, regardless of duration, provides efficient incentives for resources to be flexible and to perform well, which ultimately lowers costs to consumers and improves reliability.[176] Potomac Economics states that, together with the alignment of dispatch and settlement intervals, a requirement for RTOs/ISOs to price "transitory shortages" rewards units that can respond quickly to help the RTO/ISO remedy the shortage and, in doing so, addresses the diminished reliability caused by the shortage.[177]

122. Potomac Economics states that transitory shortages typically occur when the system is ramp-constrained, and that these are true shortages, because if a large contingency occurs during this period (*e.g.*, a generator tripping off-line), the RTO/ISO will not have the ability to replace the capacity because its other generators are already ramping as quickly as possible. Potomac Economics states that the Commission's proposal will lead to resources offering faster ramp rates, offering wider dispatch ranges and not self-scheduling resources, and offering shorter start times for natural gas turbines. Potomac Economics states that the proposal also has important long-term implications as it provides efficient incentives for participants to build more flexible, fast-ramping generating resources, and to make maintenance decisions on existing resources to increase their flexibility.[178]

123. Potomac Economics also states that allowing offline resources to set real-time energy and ancillary services prices can be efficient, but there are also conditions under which the use of these resources can artificially lower energy prices and obscure shortages.[179] Potomac Economics explains that if an RTO's/ISO's pricing model allows infeasible or uneconomic units to set prices, the offline units represent an artificial increase in real-time supply that will depress real-time prices. Further, Potomac Economics explains that the artificial increase in real-time supply can have a large effect when the system is experiencing an operating reserve or transmission shortage, which is ultimately not priced as a shortage because an offline unit has set the price.[180]

124. Potomac Economics recommends that the Commission require RTOs/ISOs to demonstrate that their real-time pricing models do not allow offline units to set prices in a manner that undermines its real-time shortage pricing. Potomac Economics believes that this can be demonstrated by the RTO/ISO describing how and when offline units set real-time prices and showing that when offline units have set price historically that they are generally committed and dispatched as well. Potomac Economics further asserts that if the RTOs/ISOs cannot demonstrate this in their compliance filing, then they may need to make changes to their pricing models to ensure that they satisfy the Commission's price formation goals.[181]

125. The PJM Market Monitor states that five-minute shortage pricing would correctly reflect actual shortage conditions and should be implemented if PJM can accurately measure the level of reserves on a five-minute basis, which the PJM Market Monitor understands that PJM currently cannot do. The PJM Market Monitor asserts that, without accurate measurement of reserves at minute-by-minute granularity, system operators cannot know with certainty that a shortage condition exists, thus masking the trigger for five-minute shortage pricing. The PJM Market Monitor recommends that if PJM cannot measure operating reserves on a five-minute basis, the Commission should direct PJM to develop methods to do so. The PJM Market Monitor asserts that if RTOs/ISOs cannot demonstrate that they can accurately measure reserves at minute-by-minute granularity, they should not implement five-minute shortage pricing until they have that capability.[182]

126. The SPP Market Monitor supports the Commission's proposal to require RTOs/ISOs to trigger shortage pricing for any dispatch interval during which a shortage of energy and operating reserves occurs. The SPP Market Monitor states that SPP's Integrated Marketplace uses administratively-determined scarcity pricing demand curves to set prices during capacity shortages. The SPP Market Monitor explains that, during shortages, quick-start and fast-ramping resources—which generally have higher costs and low capacity factors—earn a significant portion of their annual revenue. The SPP Market Monitor asserts that scarcity pricing serves as an important mechanism for sending correct price signals to these resources; however, the SPP Market Monitor states that SPP is not sending this price signal during ramp-constrained operating reserve shortages since the SPP market rules do not allow insufficient ramping capability to trigger scarcity pricing of operating reserves.[183] The SPP Market Monitor requests that the Commission address the ramp-constrained operating reserve shortage pricing issue in the Final Rule.[184]

c. Comments Supporting the Shortage Pricing Reform

127. Several other commenters express support for shortage pricing reform. These commenters agree that the proposed shortage pricing reform will increase transparency, create incentives to trigger quick response from supply, promote investment in resources that

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[172] PJM and SPP Comments at 5–6.

[173] PJM and SPP Comments at 7.

[174] PJM and SPP Comments at 8.

[175] Potomac Economics Comments at 9.

[176] Potomac Economics Comments at 7.

[177] Potomac Economics Comments at 7.

[178] Potomac Economics Comments at 8.

[179] Potomac Economics Comments at 9.

[180] Potomac Economics Comments at 10.

[181] Potomac Economics Comments at 9–11.

[182] PJM Market Monitor Comments at 9.

[183] SPP Market Monitor Comments at 4 (citing SPP Tariff, Attachment AE 5.1.2.1 and 8.3.4.2).

[184] SPP Market Monitor Comments at 4–6.

can respond to short duration shortages, and provide revenues to resources that reflect the value of the service provided.[185] In addition, several commenters, including EPSA and Westar, support the shortage pricing proposal and state that it should apply to all shortages, regardless of duration.[186]

128. Several commenters support the Commission's shortage pricing proposal, arguing that market clearing prices should reflect shortage or emergency situations so that generators are provided transparent price signals that reflect the market conditions.[187] EPSA and Westar note that reflecting a shortage price signal during transient shortage events will result in a price signal that incents resources to respond to real-time system constraints based on a price that reflects the value of loss of load even if the event is less than ten minutes in duration.[188] Further, Westar states that if the "steepness" of regulation and operating reserve demand scarcity pricing curves is a concern then an RTO/ISO should create separate operating reserve scarcity demand curves for transitory periods versus periods lasting longer than ten minutes.[189]

129. Some commenters state that the shortage pricing proposal will provide an incentive for existing resources to offer their supply and to be available if shortages occur and will provide an incentive for incremental investments to enable existing or new generation or dispatchable demand to respond to shortages, regardless of duration.[190] Further, CEA states that without appropriate compensation prices invariably become distorted insofar as they do not reflect the increased value of that resource with utmost accuracy and granularity.[191] In addition, NGSA comments that the proposal will encourage investments by generators that allow them to more reliably perform, leading to greater regional fuel assurance.[192]

130. ANGA states that while a shortage may be transient and last only a single five-minute interval, some resources are able to move quickly enough to meet these shifts in demand and, hence, reduce overall system instability. Further, ANGA maintains, allowing prices to respond to these small shortages also sends a long-term price signal to the market, highlighting where and what types of resources are needed on the system, which improves overall system reliability. ANGA also agrees with EPSA's position, recorded in the NOPR, that all markets should prioritize establishing shortage pricing based on operating reserve demand curves and co-optimized with the energy market. ANGA states that this is a least-cost solution and recommends that the Commission direct the RTOs/ISOs to include in their compliance filing a plan for modifying their rules, to the extent necessary, to include these features in both the day-ahead and real-time markets.[193]

131. Powerex supports the Commission's proposal to require RTOs/ISOs to apply shortage pricing for any dispatch interval during which a shortage of energy or operating reserves occurs.[194] Powerex contends that shortage pricing mechanisms tied to real-time conditions provide revenues to generators and demand side resources that provide energy and reserves when needed, which is an advantage over the capacity markets long-term focus on load growth and reliability.[195]

132. EDP Renewables states that the Commission's shortage pricing proposal would result in more accurate price signals than under existing market rules, and therefore would encourage greater investment in new production and storage technologies with the ability to respond quickly to shortages.[196] Similarly, ESA asserts that the shortage pricing reform will improve the ability for a resource to be compensated based on the value of the service the resource provides.[197] ESA maintains that, for energy storage resources to help ensure grid reliability, an economic incentive must exist to incorporate those resources onto the grid.[198]

133. Exelon and Inertia Power assert that implementing shortage pricing for any interval during which a shortage could occur will provide the right incentives for generating resources and will promote adequate incentives for resource adequacy. Exelon and Inertia Power state that it is economically more efficient for prices to reflect the value of the marginal resource during shortage periods, and that this is particularly true in instances where generation resources must compete with alternatives, such as exporting power to a neighboring market or not consuming a scarce fuel.[199]

134. PSEG states that it supports the shortage pricing proposal, that the proposal would address concerns about transparency, and that it would accomplish Order No. 719's objective of enhancing market efficiency by establishing a price that reflects the value of the loss of load and encourage resources to respond to shortage events.[200] PSEG further states that the absence of shortage pricing in the appropriate intervals is inefficient within individual RTOs/ISOs as well as between them, and it can frustrate the objectives of Coordinated Transaction Scheduling, which is currently being deployed by several RTOs/ISOs.[201]

135. Golden Spread supports the Commission's proposed shortage pricing reform and argues that even the smallest amount of operating reserve and energy shortage should be reflected in scarcity pricing.[202] Golden Spread states that it has invested hundreds of millions of dollars in a fleet of new quick-start, fast-ramping generation resources in anticipation of the proper working of efficient marginal cost-based energy markets. Golden Spread states that to the extent these resources are not fully compensated because shortage pricing is masked, the value of these assets to Golden Spread's members and their consumers is diminished.[203]

136. DTE states that, as a member of MISO, it has largely supported the changes MISO has made through ELMP to ensure that generators are provided

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[185] Ameren Comments at 1, 3–4; ANGA Comments at 2–5; CAISO Comments at 2; CEA Comments at 3–6; Dominion Comments at 1–2; DTE Comments at 3–4; EDP Renewables Comments at 2; EEI Comments at 2; ESA Comments at 2–4; Entergy Nuclear Power Marketing Comments at 2; EPSA Comments at 1–5; Exelon Comments at 4; Financial Marketers Coalition Comments at 1; Golden Spread Initial Comments at 1–3; Inertia Power and DC Energy Comments at 2; ISO–NE Comments at 1; MISO Comments at 2, 9; NEI Comments at 1; NGSA Comments at 2–5; PJM Power Providers Comments at 2–5; Potomac Economics Comments at 2; Powerex Comments at 6; PSEG Comments at 3; Public Interest Organizations Comments at 5; SPP Market Monitor Comments at 2; Westar Comments at 1; Duke Comments at 7.

[186] EPSA Comments at 9; EPSA Comments, Pope Aff. at 15; Golden Spread Initial Comments at 6; PJM Power Providers Comments at 4; Powerex Comments at 6; EDP Renewables Comments at 5–6; Entergy Nuclear Power Marketing Comments at 2; Exelon Comments at 6; PSEG Comments at 13; Westar Comments at 5; NEI Comments at 14; CEA Comments at 4; NGSA Comments at 5.

[187] EEI Comments at 10; EPSA Comments at 9; PJM Power Providers Comments at 4; Westar Comments at 5; NEI Comments at 14.

[188] EPSA Comments at 9; Westar Comments at 5.

[189] Westar Comments at 5.

[190] EPSA Comments, Pope Aff. at 15; NEI Comments at 14; CEA Comments at 4; NGSA Comments at 5.

[191] CEA Comments at 4.

[192] NGSA Comments at 5.

[193] ANGA Comments at 5.

[194] Powerex Comments at 6.

[195] Powerex Comments at 8.

[196] EDP Renewables Comments at 5–6.

[197] ESA Comments at 4.

[198] ESA Comments at 4.

[199] Inertia Power and DC Energy Comments at 5; Exelon Comments at 6.

[200] PSEG Comments at 13.

[201] PSEG Comments at 14.

[202] Golden Spread Reply Comments at 4.

[203] Golden Spread Reply Comments at 7.

accurate price signals, akin to the shortage pricing proposal.[204]

d. Comments Recommending Changes to the Shortage Pricing Reform

137. Several commenters propose changes to the shortage pricing reform, or identify implementation issues in specific RTOs/ISOs.

138. Golden Spread, for example, states that the current SPP rules allow the temporary use of operating reserves to meet energy requirements during transient periods without invoking shortage pricing; in other words, SPP's rules encourage "price manipulation" undermining the transparency needed to incentivize longer term economic and reliable solutions.[205]

139. Golden Spread identifies examples of issues with certain SPP processes that it argues need to be addressed to comply with this reform and provides the following recommendations to resolve them: (1) Relax constraints to allow economic dispatch to solve when there is a resource capacity constraint, global power balance constraint, resource ramp constraint or operating constraint;[206] (2) prevent insufficient ramping capability to be subject to scarcity pricing;[207] (3) include fast-start technologies in a Reliability Unit Commitment action to avoid scarcity events, which then eliminates scarcity prices;[208] and (4) use of the concept of "head-room" to not factor much-needed ramping capacity in the LMP, which is reducing transparency and creating large uplifts.[209]

140. ELCON states that the shortage pricing proposal should be adopted only if the Commission promotes the development of technology-neutral fast-ramp products paid to provide the specific shortage service, and for which compensation would not inflate real-time LMPs.[210] ELCON asserts that it conditionally supports the provision on shortage price triggers when applied to technology-neutral fast-ramping products—products it states could be provided by demand response, energy storage technologies, or generation—but not to real-time shortage pricing in which every resource dispatched or called by the system operator during a dispatch interval is paid the same price.[211]

e. Comments Opposed to the Proposed Shortage Pricing Reform

141. Several commenters oppose the shortage pricing proposal. Several commenters argue that while the NOPR does not address the price level of the shortage pricing, to the extent that RTOs/ISOs do change shortage pricing triggers, the RTOs/ISOs should also evaluate whether shortage pricing levels remain just and reasonable.[212] For example, Concerned Cooperatives and APPA and NRECA argue that the NOPR will raise prices for consumers, but the Commission fails to quantify the cost impact of the shortage pricing proposal on consumers or the potential benefits to the market and consumers.[213] Concerned Cooperatives add that any changes to the shortage pricing triggers in the RTO/ISO markets must be cost-justified on the basis of quantifiable improvements in market efficiencies and cost reductions. Furthermore, Concerned Cooperatives argue that the Commission's shortage pricing will raise prices for consumers and increase revenues to incumbent generators.[214]

142. APPA and NRECA assert that it is important to understand how various resource types would respond to price signals created by the shortage pricing proposal. Specifically, they assert that the NOPR did not discuss whether a five-minute shortage pricing event would produce a sufficient response or only reflect a transient shortage resolvable without resorting to shortage pricing.[215] APPA and NRECA reference PJM representative Adam Keech's comment at the October 28, 2014 workshop on scarcity and shortage pricing, justifying PJM's current minimum duration of 30 minutes prior to triggering shortage pricing, and assert that the shortage pricing proposal runs the risk of rewarding generators that are already online just because another generator has not fully ramped up yet.[216] APPA and NRECA state that the NOPR neither discussed the degree to which the RTOs/ISOs are already in compliance with the proposal, the extent to which implementation would impact the frequency of shortage pricing events or impact prices, nor did it require RTOs/ISOs to undertake this analysis.[217] APPA and NRECA state that shortage pricing was triggered relatively infrequently in PJM and MISO, but more frequently in NYISO.[218]

143. APPA and NRECA question the extent to which shortage pricing would improve short-term system efficiency. They comment that existing variations among RTOs/ISOs in shortage pricing approaches create an opportunity to analyze the efficacy of more frequent shortage events. They request that the Commission direct the RTOs/ISOs to provide evidence or examine whether the theoretical benefits of the shortage pricing proposal can be validated with actual resource decisions. APPA and NRECA caution that, without such analysis, entities, such as generators already online that cannot easily ramp up or down or financial marketers, could benefit financially without contributing to system efficiency.[219] Concerned Cooperatives also note that the Commission's rationale that prices must rise to reflect the true value of generation offered during operational shortages for the market to function properly fails to consider that only half of the market, *i.e.*, generators, may be able to respond to the price signal in real-time.[220]

144. On the topic of long-term incentives, several commenters assert that no evidence exists that price signals as volatile and transient as shortage prices would be the basis for capital investments, whether to improve flexibility, whether to delay or avoid retirements, and especially not for the construction of new resources. APPA and NRECA assert that, even with a slight uptick in merchant plant construction compared to prior years, 95 percent of new construction was built under contract in 2014, and 98 percent of new construction was built under contract in 2013.[221] Further, Concerned Cooperatives argue that the evidence presented at the technical conferences preceding the NOPR demonstrate that short-term price signals from shortage pricing do not result in the long-term resource investment contemplated in the NOPR.[222]

145. Concerned Cooperatives contend that the RTOs/ISOs could develop better products, such as a fast-ramping product, that could encourage investment in more flexible resources without having to pay every resource a high price during shortage intervals of short duration.[223] Moreover, APPA and

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[204] DTE Comments at 5.

[205] Golden Spread Reply Comments at 5.

[206] Golden Spread Comments at 8.

[207] Golden Spread Comments at 7–8.

[208] Golden Spread Comments at 9–10.

[209] Golden Spread Comments at 10.

[210] ELCON Comments at 2.

[211] ELCON Comments at 3–6.

[212] APPA and NRECA Comments at 12; TAPS Comments at 14–15; Concerned Cooperatives Comments at 13.

[213] Concerned Cooperatives Comments at 13–14; APPA and NRECA Comments at 6.

[214] Concerned Cooperatives Comments at 13.

[215] APPA and NRECA Comments at 6–7.

[216] APPA and NRECA Comments at 7.

[217] APPA and NRECA Comments at 9.

[218] APPA and NRECA Comments at 9–10.

[219] APPA and NRECA Comments at 10–11.

[220] Concerned Cooperatives Comments at 14.

[221] APPA and NRECA Comments at 11–12; TAPS Comments at 7–13; Concerned Cooperatives Comments at 15–16.

[222] Concerned Cooperatives Comments at 15–16.

[223] Concerned Cooperatives Comments at 22–24.

NRECA encourage the Commission to examine alternative methods of achieving its stated goal of incentivizing the availability of resources during periods of shortage, such as separately priced ramping products. APPA and NRECA urge the Commission to also examine whether such methods might achieve this goal at a lower cost to consumers.[224] Concerned Cooperatives further argue that the Commission's proposal is simply a transfer of wealth from consumers to generators without value to consumers, because, as the Commission admitted in the NOPR, some shortage events are so short that suppliers cannot react to the price signal.[225]

146. ODEC states that, in the example provided by PJM, if a unit is slow in coming online for a five-minute interval, it is not clear that shortage pricing would not over-compensate a resource, or if supply can even respond to such a short-term event in sufficient time for the price signal to create an incentive to change behavior. ODEC states that it therefore believes that shortage pricing during transient shortages may be unjust and unreasonable because it will increase prices paid by load without corresponding benefits.[226]

147. APPA and NRECA also express concern that more frequent shortage pricing creates incentives to exercise market power and game market rules due to the potential for higher energy and operating reserve prices. They assert that if the proposal moves forward, each RTO/ISO should be required to reevaluate its market power mitigation rules and propose new or additional mitigation measures if necessary.[227] In addition, Concerned Cooperatives also argue that revising RTO/ISO tariffs to invoke shortage pricing more frequently is likely to increase opportunities for exploitation of consumers, but that the NOPR does not propose to require RTOs/ISOs to include in their compliance filings an analysis of needed reforms to ensure that consumers remain protected against the exercise of market power.[228]

148. Concerned Cooperatives also argue that if the Commission issues a final rule in this proceeding, RTOs/ISOs must be required to demonstrate that their shortage pricing mechanisms comply with four overarching principles, by providing for (1) prices that reflect the marginal costs of meeting the shortage; (2) a cap that is designed to mitigate adverse financial impacts on parties who are short; (3) prices that escalate with greater levels of shortage, because marginal costs will vary by shortage; and (4) a mechanism to ensure that revenues earned through shortage pricing are not duplicated by capacity market revenues.[229]

149. The New Jersey Board urges the Commission to allow PJM to retain its current shortage pricing mechanism—a thirty-minute look-ahead dispatch algorithm that identifies reserve shortages as only those lasting a minimum of thirty minutes. The New Jersey Board agrees with PJM that five-minute shortfalls are not necessarily symptomatic of system stress, but are merely transient shortfalls that can be quickly addressed through system re-dispatch.

150. More broadly, TAPS argues that any price signal during transient scarcity events is meaningless because resources cannot respond in time to the higher prices.[230] In addition, Direct Energy says that targeting transient shortages will create control issues and increase uplift, and the application of RTO/ISO shortage penalty factors to these transient situations will likely lead to higher prices than would otherwise be produced, creating unjust and unreasonable rates for generation compensation.[231]

151. Regarding definitions, Direct Energy asserts that a true shortage implies that insufficient capacity exists on an RTO's/ISO's system to meet energy and reserve requirements. In contrast, Direct Energy argues, transient shortage conditions are not true shortages because they simply reflect the operating characteristics of the generators being used to meet energy and reserve targets. Direct Energy argues that in a transient shortage condition, the RTO/ISO has the capacity to meet energy and reserve requirements and the transient shortage period represents the period of time it takes to deploy generation resources to meet those targets.[232]

152. Direct Energy claims the response an RTO/ISO receives based on the shortage pricing signals sent during transient shortage conditions is likely to cause a control issue when generation already being ramped through RTO/ISO dispatch to resolve the shortage condition hits its dispatch targets. Further, Direct Energy argues unjust and unreasonably higher prices would result from targeting "transient" shortages because of the impact of shortage pricing penalty factors in transient shortage circumstances, because the shortage pricing reserve penalty factors would be applied to a marginal unit providing energy that is not the highest opportunity cost reserve unit. Thus, Direct Energy argues the Commission should either revise its proposal to reflect issues with transient shortages of operating reserves, or permit individual RTOs/ISOs to evaluate this proposal and consider tariff revisions to address true shortages and to send appropriate price signals.[233]

153. Concerned Cooperatives and APPA and NRECA argue that the NOPR does not account for differences among the RTOs/ISOs, maintaining that shortage pricing issues should be resolved through individual stakeholder processes.[234] Alternatively, Concerned Cooperatives request that the Commission not implement shortage pricing reform until an RTO/ISO demonstrates that it has eliminated the conditions that cause "artificial" shortages (those arising from mathematical modeling when no actual operational shortage exists), adopts rules preventing shortage pricing from being applied during artificial shortages, and adopts rules ensuring that shortage price levels are reduced during artificial shortages to reflect that these are not real shortages.[235]

154. Concerned Cooperatives also note that the NOPR fails to provide a comparison of the market design in RTO/ISO-administered markets that trigger shortage pricing for a shortage event of any duration and those that use longer duration events as the trigger.[236] Concerned Cooperatives argue that, before imposing a uniform rule, the Commission should determine whether these different shortage pricing rules have resulted in incremental resource development, improved generator response to shortage conditions, and/or reduced the need for uplift charges. Concerned Cooperatives state that in some cases, uplift payments may be the most cost-effective solution for consumers.[237]

155. Several commenters point to various efforts in RTOs/ISOs that may impact shortage pricing. Concerned Cooperatives argue that the Commission should not address price formation issues in a piecemeal fashion, as changes to one element will impact the

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[224] APPA and NRECA Comments at 12.

[225] Concerned Cooperatives Comments at 15–16.

[226] ODEC Comments at 6.

[227] APPA and NRECA Comments at 15–16.

[228] Concerned Cooperatives Comments at 15.

[229] Concerned Cooperatives Comments at 24–25.

[230] TAPS Comments at 7–13.

[231] Direct Energy Comments at 10–11.

[232] Direct Energy Comments at 10–11.

[233] Direct Energy Comments at 11–13.

[234] APPA and NRECA Comments at 5; Concerned Cooperatives Comments at 18.

[235] Concerned Cooperatives Comments at 18.

[236] Concerned Cooperatives Comments at 26.

[237] Concerned Cooperatives Comments at 26.

need for other reforms. Concerned Cooperatives note that several RTOs/ISOs already have rules providing adequate incentives for resource performance and investment, such as PJM's Reliability Pricing Model, ISO–NE's Forward Capacity Market, or MISO's ELMP.[238] Concerned Cooperatives assert that the Commission provides no evidence that more frequent triggering of shortage pricing is necessary to ensure resource adequacy or improve resource performance and flexibility when RTOs/ISOs use other market tools to achieve the same objectives set forth in the NOPR.

156. The New Jersey Board, APPA and NRECA and ODEC all acknowledge PJM's Capacity Performance Program[239] and argue to varying degrees that shortage pricing need not be considered here given this PJM reform or that the Commission should consider whether there would be overlap between this PJM reform and the shortage pricing proposal.[240] Furthermore, APPA and NRECA state that another factor in determining whether the shortage pricing proposal would improve market efficiency and benefit consumers is the extent to which there is an overlap between this proposal and other RTO/ISO market rules.[241] APPA and NRECA also point out that, in some RTOs/ISOs such as NYISO, scarcity pricing is an additional and separate revenue stream that can balance reliance on capacity market revenues.[242] Further, ODEC suggests that, instead of requiring an expansion of scarcity pricing to transient time periods, the Commission require PJM to consider the need to reduce, if not eliminate, scarcity pricing in light of the new Capacity Performance construct.[243]

157. Concerned Cooperatives note that the NOPR fails to identify the number of additional shortages that would be triggered in RTO/ISO markets that do not invoke shortage pricing for a single settlement interval. They argue that the NOPR also fails to quantify what that cost might potentially be for consumers, particularly in PJM, which recently sought to increase its energy offer caps to $2,000 per MWh which could produce LMPs of $3,700 per MWh during shortage events. Concerned Cooperatives state that the NOPR provides no evidence that prices at this level are just and reasonable for a five-minute shortage where a resource cannot respond and/or the event is triggered by an artificial shortage.[244]

158. PG&E urges the Commission to examine transient shortages and their attendant price spikes, and resolve modeling issues that are causing these shortages. PG&E understands that shortage pricing might be appropriate to the extent that such pricing provides a meaningful price signal to resources. However, PG&E argues that most price spikes in the CAISO over the past five years have been so short that they have not provided a meaningful opportunity for resources to respond.[245] For example, PG&E states that from 2012 through 2014, the CAISO five-minute market saw positive price spikes (>$250/MWh) in approximately 0.75 percent of the intervals. PG&E argues that transitory price spikes do not contribute to market efficiency, but result in increased market costs, and they give false signals to virtual participants, which can distort day-ahead awards and prices. PG&E also asserts that these transitory price spikes have contributed to price divergence between day-ahead and real-time and have resulted in significant uplift costs.[246]

159. PG&E notes that CAISO is already taking significant steps to address modeling issues that create transient shortages and attendant transient price spikes. For example, PG&E states that CAISO is working to augment the real-time dispatch function with a Flexible Ramping Product which will help avoid ramp-induced shortages that cause scarcity conditions in real-time. PG&E also explains that CAISO is considering applying different penalty prices for infeasibilities depending on the level of constraint relaxation, which will more appropriately reflect the cost of constraint violations. PG&E asserts that a small violation of the power balance constraint may be covered by deploying regulation reserves at a smaller cost per megawatt-hour than a larger violation, which may require more costly load shedding.[247]

160. Dominion states that it is concerned that some shortages are merely transient in nature due to slight differences in modeling and the ramping of generation, and may not warrant sending a shortage price signal to the market. Dominion argues that issues regarding transient shortages should be addressed prior to implementation of the proposed reforms.[248] Dominion states that the Commission should require RTOs/ISOs to specifically explain how the RTOs/ISOs will address this issue as part of their compliance filings. Further, Dominion asserts that the modification of shortage pricing triggers to better correlate to dispatch intervals should coincide with implementation of the Commission's proposal to align settlement intervals with dispatch intervals. Dominion argues that this will align a resource's timely response to shortage pricing with payment for its response.[249]

4. Commission Determination

161. For the reasons discussed below, we adopt the NOPR shortage pricing proposal and modify the regulatory text to clarify that shortage pricing is required only when a shortage of energy or operating reserves is indicated by the RTO's/ISO's software.

162. Specifically, we require each RTO/ISO to trigger shortage pricing for any interval in which a shortage of energy or operating reserves is indicated during the pricing of resources for that interval. As stated in the NOPR, the shortage pricing requirement should "ensure that a resource is compensated based on a price that reflects the value of the service the resource provides."[250] This rationale applies to any shortage "regardless of the duration or cause of [the] shortage."[251] It thus would apply to "transient shortages." Several commenters specifically agreed with this analysis.[252] Under this requirement, whenever a shortage of energy or operating reserves is indicated in an RTO's/ISO's pricing run software for a particular pricing interval, shortage pricing should be invoked even if during that period resources are ramping up to a particular level they are likely to reach in a few minutes.

163. We find that the shortage pricing requirement will help ensure that prices rise sufficiently and appropriately to allow supply to meet demand during an operating reserve shortage, and thus will more accurately reflect the value a

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[238] Concerned Cooperatives Comments at 18–21.

[239] *See PJM Interconnection, L.L.C.*, 151 FERC ¶ 61,208 (2015).

[240] New Jersey Board Comments 4–6; APPA and NRECA Comments at 14.

[241] APPA and NRECA Comments at 13.

[242] APPA and NRECA Comments at 14–15.

[243] ODEC Comments at 8.

[244] Concerned Cooperatives Comments at 25.

[245] PG&E Comments at 1–2.

[246] PG&E Comments at 1–2.

[247] PG&E Comments at 2.

[248] Dominion Comments at 4–5.

[249] Dominion Comments at 5.

[250] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 52.

[251] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 47; *see also id.* P 9 ("This reform would also ensure that resources operating during a shortage are compensated for the value of the service that they provide, regardless of whether the shortage is short-lived.").

[252] *See, e.g.*, Inertia Power and DC Energy Comments at 6 (citing NYISO Comments, Docket No. AD14–14–000, at 28–29 (Mar. 6, 2015), Potomac Economics Comments, Docket No. AD14–14–000, at 25–26 (Mar. 6, 2015), and Calpine Comments, Docket No. AD14–14–000, at 20 (Mar. 6, 2015)); SPP Market Monitor Comments at 3; Golden Spread Comments at 3–4.

resource provides.[253] Better formed prices help ensure just and reasonable rates by providing appropriate incentives for market participants to follow commitment and dispatch instructions, maintain reliability, provide transparency of the underlying value of the service so that operational and investment decisions are based on prices that reflect the actual marginal cost of serving load and the operational constraints of reliable system operation, and encourage efficient investments in facilities and equipment.

164. As for incentives to follow dispatch, as noted in the NOPR, if a resource is compensated based on a price that reflects the value of the service the resource provides, the resource will have appropriate incentives to address energy or reserve shortages. As explained by Potomac Economics, the higher prices (relative to non-shortage price intervals) resulting from the shortage pricing proposal will enhance resource flexibility by leading to: (1) Faster resource ramp rates; (2) wider dispatch ranges and not self-scheduling resources; (3) shorter start times for natural gas turbines; and (4) an incentive to build more flexible, fast-ramping generating resources and to perform maintenance on existing resources that increases their flexibility.[254] In addition, shortage pricing during all reserve deficiencies also sends the correct price signal to already operating resources to take any actions necessary to remain operational during the shortage event. For instance, a resource that is already operating but realizes it will need to take a forced outage in the near-term will receive a clear signal to delay that forced outage, to the extent possible, until the reserve shortage has been resolved.

165. A number of commenters cite the role of appropriate shortage pricing in creating an incentive for market participants to make investments that will alleviate shortages in the future.[255] EDP Renewables and ESA note that the shortage pricing proposal will encourage greater investment in new production and storage technologies.[256] In response to commenters that assert that short duration shortage prices will not create a sufficient incentive for new entry, we agree with EPSA that appropriate shortage pricing will encourage more modest investments that can improve availability and response-time, such as weatherization of fuel supplies, heat tracing to reduce instrument failure during freezing temperatures, and completion of deferred maintenance such as burner upgrades.[257] Investments of the nature identified by commenters should enhance reliability in the long-run as system resources are more able to perform during critical system conditions.

166. With regard to transparency, an RTO's/ISO's action to establish prices at the times of shortage, including transient shortages, makes the shortage apparent to all market participants. This maximizes the opportunities and incentives for all system resources to take actions to address the shortage.

167. In response to commenters like CAISO, we clarify that we did not intend to impose shortage pricing if a shortage occurs during an interval for which the prices and dispatch decisions have already been set. We did not intend that, for example, *ex post* pricing should, after binding prices have been determined by the RTO/ISO software, invoke shortage pricing based upon a subsequent recognition that a shortage existed in a particular prior interval. Similarly, the shortage pricing proposal also did not intend to require any changes to the frequency of existing dispatch and pricing runs for energy or operating reserves. To the extent that operating reserves are priced at a different interval than energy resources are dispatched, as is the case in CAISO, this Final Rule applies to the interval that prices and co-optimizes both energy and operating reserves. Thus, an RTO/ISO need not trigger shortage pricing during a fifteen-minute operating reserve period if it becomes aware of a shortage within that interval, because reserve prices have already been set for that entire fifteen-minute period. Only if that shortage is projected to continue into the next reserve period and there is time to factor that shortage into the dispatch and pricing run for the next interval does the RTO/ISO need to trigger shortage pricing for that next interval.

168. Also, the shortage pricing proposal did not intend to require any changes to existing pricing methods, such as ELMP in MISO that allows offline resources to set energy prices, and we agree that the use of offline resources can result in efficient pricing.[258] However, we agree with Potomac Economics that if an RTO's/ISO's pricing model allows infeasible or uneconomic units to set prices, the offline units represent an artificial increase in real-time supply that will depress real-time prices. Therefore, for the purpose of this Final Rule, RTOs/ISOs choosing to use offline resources to count towards energy and operating reserve requirements may not allow infeasible or uneconomic offline units to set prices through the real-time pricing model or to be counted as providing reserves.

169. In opposing the proposal, PJM and SPP argue that an energy or operating reserve shortage that the RTO/ISO expects to be resolved quickly (*e.g.*, within ten minutes), should not trigger shortage pricing. They note that, in PJM, for example, shortage pricing is not triggered until a shortage is projected to last at least thirty minutes.[259]

170. We disagree that an energy or operating reserve shortage that the RTO/ISO expects to be resolved quickly should not trigger shortage pricing. Such a shortage presents exactly the type of mismatch between system conditions and pricing that the reform was meant to remedy. Thus, by adopting the proposed shortage pricing reform, we require PJM and SPP to modify their existing shortage pricing mechanisms.

171. As summarized above, PJM and SPP provide three hypothetical situations in their joint comments to describe situations where they argue shortage pricing should not apply.[260] In all of these scenarios, RTOs/ISOs are "technically compromising the operating reserve requirement," as PJM and SPP concede,[261] although such transient shortages may not violate NERC's reliability standards.[262] However, we find that RTOs/ISOs should reflect these system conditions in the price. Using shortage pricing for a transient shortage situation reflects in

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[253] *See* NOPR, FERC Stats. & Regs. ¶ 32,710 at P 48 (citing Order No. 719, FERC Stats. & Regs. ¶ 31,281).

[254] Potomac Economics Comments at 8.

[255] NEI Comments at 14; NGSA Comments at 5; EPSA Comments, Pope Aff. at 15; Potomac Economics Comments at 8.

[256] EDP Renewables Comments at 5–6; ESA Comments at 4. ESA states that the shortage pricing reform will improve the ability for a resource to be compensated based on the value of the service the resource provides.

[257] EPSA Comments, Pope Aff. at 19.

[258] *See Midcontinent Indep. Sys. Operator, Inc.*, 150 FERC ¶ 61,143, at P 36 (2015) ("For the reasons discussed below, we conditionally accept MISO's Revised ELMP Filing, effective March 1, 2015, subject to a further compliance filing. . . ."); *Midcontinent Indep. Sys. Operator, Inc.*, Docket No. ER15–685–001 (Feb. 4, 2016) (delegated letter order accepting compliance filing).

[259] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 46 & n.70; PJM and SPP Comments at 5.

[260] PJM and SPP Comments at 3–5.

[261] PJM and SPP Comments at 4.

[262] Requirement R6.2 of North American Electric Reliability Corporation's Reliability Standard BAL–002–1 requires restoration of contingency reserves within 90 minutes: "The default Contingency Reserve Restoration Period is 90 minutes." In the Western Electric Coordinating Council (WECC), the reliability standards require restoration of contingency reserves within 60 minutes. WECC BAL–002–WECC–2, R1.

the price of operating reserves the current system conditions, which include the possibility of a contingency occurring—for which operating reserves were procured and designed to address. This is designed to appropriately value those resources that provide value to the system by their ability to respond quickly to changing prices. As Potomac Economics states,[263] transient shortages, which typically occur when the system is ramp-constrained, are true shortages because, if a large contingency occurs during such a shortage (*e.g.*, a generator trips off-line), the RTO/ISO will not have the ability to replace the capacity because other generators are already ramping as quickly as possible. It is possible, as PJM and SPP state, that when a transient shortage is recognized, RTOs/ISOs can re-dispatch their system to eliminate the shortage quickly.[264] However, until the shortage is resolved, prices should reflect the system conditions and the actions taken to resolve the shortage as much as possible.

172. PJM, SPP, and Direct Energy have also not shown that applying shortage pricing to transient shortages will create control issues and increase uplift.[265] In fact, there is evidence in this record that it will not. The RTOs/ISOs which currently invoke shortage pricing during relatively brief periods, *i.e.*, MISO, NYISO and ISO–NE., do not appear to have these types of control issues. Further, we note that reflecting system conditions in prices should decrease uplift over time, as the costs of units committed, dispatched, or designated as reserves would be reflected in prices and those units would no longer need to be made whole through uplift payments.

173. PJM and SPP state that application of the shortage pricing reform to transient shortages would likely require the implementation of operating reserve demand curves that distinguish prices relative to varying degrees of shortage.[266] In the NOPR, the Commission acknowledged that, as a result of the shortage pricing reform, "an RTO/ISO may need to calibrate administrative shortage prices to better reflect the value of the service." [267] Thus, if PJM or SPP believes that a modification of the applicable operating reserve demand curves is appropriate in light of the shortage pricing reform, the appropriate forum to make such is a change is through an FPA section 205 filing.

174. We disagree with TAPS, Concerned Cooperatives, APPA, and NRECA that the only effect of requiring RTOs/ISOs to trigger shortage prices in transient events is to provide extra revenue to generators already in the market.[268] While extra revenue may result from prices accurately reflecting shortage conditions, we believe that is appropriate. The purpose for requiring the shortage pricing is to create transparent market prices that reflect system conditions. The benefit of triggering shortage prices for all shortages is that it gives all suppliers an incentive to do as much as they can, including investments and operational alterations, to be available the next time it appears that shortages may occur and shortage pricing may be invoked, even if such shortages last briefly. Further, as discussed above, shortage pricing during all reserve deficiencies also sends the correct price signal to already operating resources to take any actions necessary to remain operational during the shortage event.

175. We disagree with the views of those commenters [269] who assert that the proposed rule is not justified because no evidence exists that price signals as volatile and transient as shortage prices would be the basis for capital investments. While shortage pricing revenues may not, by themselves, be enough to financially justify entirely new generation projects, commenters who are generation owners and project developers have indicated that triggering shortage prices during short duration shortages as proposed in the NOPR "will provide an incentive for incremental investments to enable existing or new generation or dispatchable demand to respond to short-duration shortages." [270] As to the amount of construction done recently by merchants as opposed to that done under long-term contracts, we note that RTOs/ISOs such as PJM have been able to maintain reliability with reliance primarily upon their capacity market and not long-term contracts for new generation.[271]

176. TAPS recommends that the Commission direct each RTO/ISO to propose new shortage prices for transient shortages that do not exceed the value of the incremental benefit (if any) provided by an additional megawatt in those circumstances, or to demonstrate that the RTO's/ISO's existing shortage prices applicable in such circumstances already meet that standard.[272] We decline to require this in the Final Rule both because this was not originally proposed and because the record in this proceeding has not persuaded us that any RTO's/ISO's administrative shortage prices need to be modified. However, as discussed above, any RTO/ISO may file, pursuant to section 205 of the FPA, to propose a modification of any of the administrative shortage prices as a result of this Final Rule, as PJM and SPP indicate they might.

177. The PJM Market Monitor identifies an implementation issue, which may be unique to PJM. The PJM Market Monitor asserts that PJM cannot accurately measure the actual level of operating reserves on a five-minute basis. To address this, the PJM Market Monitor and the New Jersey Board recommend that the Commission direct PJM to develop this measurement capability before it implements the shortage pricing proposal.[273] To the extent that PJM or any other RTO/ISO believes it needs to enhance its measurement capabilities to implement the shortage pricing requirement, it should propose to do so in its compliance filing.

178. Concerned Cooperatives maintains that the shortage pricing proposal may not achieve the price formation objective of increased transparency because generators may not be capable of responding fast enough to shortage pricing triggered during transient events.[274] However, we find that the shortage pricing requirement will increase transparency because shortage prices provide a clear and public market signal, while compensation to resources provided through uplift provides a signal only to individual resources and after-the-fact. In addition, consistently sending a clear price signal during reserve deficiencies in real-time should encourage market participant behavior in the day-ahead market that translates into day-ahead

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[263] Potomac Economics Comments at 8.

[264] PJM and SPP Comments at 4.

[265] *See* PJM and SPP Comments at 3–5 (making this argument in the context of the hypotheticals discussed above); Direct Energy Comments at 10–11.

[266] PJM and SPP Comments at 7–8.

[267] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 49.

[268] TAPS Comments at 9; APPA and NRECA Comments at 7; Concerned Cooperatives Comments at 16.

[269] APPA and NRECA Comments at 11–12; TAPS Comments at 7–13; Concerned Cooperatives Comments at 15–16.

[270] EPSA Comments, Pope Aff. at 15.

[271] *See generally* Monitoring Analytics, *New Generation in the PJM Capacity Market: MW and Funding Sources for Delivery Years 2007/2008 through 2018/2019* (May 4, 2016), *http://www.monitoringanalytics.com/reports/Reports/2016/New_Generation_in_the_PJM_Capacity_Market_20160504.pdf.*

[272] TAPS Comments at 13. PJM and SPP indicate that they may need to file to modify their shortage prices. *See* PJM and SPP Comments at 8.

[273] PJM Market Monitor Comments at 9.

[274] Concerned Cooperatives Comments at 6.

prices that better reflect expected system conditions.

179. Concerned Cooperatives, ODEC, ELCON, and PG&E suggest that the Commission should not adopt the shortage pricing proposal because other initiatives, such as PJM's Reliability Pricing Model modifications and fast ramping products, already provide adequate incentives for resource performance and send the signals needed for generation investment.[275] We are not persuaded by these arguments. While other initiatives, such as PJM's Reliability Pricing Model modifications and additional fast-ramping products, could decrease the occurrence of shortages and shortage pricing, an effective shortage pricing trigger is still required to ensure appropriate pricing when shortages occur. This is particularly important for incenting behavior by load in the day-ahead market that is consistent with expected system conditions in real-time. For instance, the Reliability Pricing Model modifications will send real-time price signals to encourage resource performance, but will not necessarily encourage accurate day-ahead load forecast for load.

180. Concerned Cooperatives express concern that the Commission does not require the RTOs/ISOs to include, in their compliance filings, an analysis to ensure that consumers remain protected against the exercise of market power when the proposed reforms are implemented.[276] However, Concerned Cooperatives do not explain why the RTOs'/ISOs' existing market power mitigation methodologies would not prevent the exercise of market power during times of shortage pricing, under the proposed reforms or otherwise. Therefore, we do not require the RTOs/ISOs to provide a market power review and mitigation reforms in their compliance filings.

C. Compliance and Implementation

1. Commission Proposal

181. In the NOPR, the Commission proposed that RTOs/ISOs submit compliance filings on both the proposed settlement reform and the proposed shortage pricing reform four months from the effective date of the Final Rule; that the proposed settlement reform become effective twelve months from the date of the compliance filings for implementation of reforms to settlement systems; and that the shortage pricing proposal become effective four months from the date of the compliance filings for implementation of reforms to shortage pricing triggers.[277]

2. Comments

182. As described below, some commenters sought more time to submit compliance filings and questioned (1) whether the Commission provided enough time to implement the settlement proposal; and (2) whether the Commission should extend implementation of the shortage pricing proposal to allow for simultaneous implementation of shortage pricing proposal with the settlement proposal.

a. Comments From RTOs/ISOs

183. The ISO/RTO Council argues that the Commission should not force the RTOs/ISOs to substantially reform their existing market structure to comply with the shortage pricing proposal.[278] PJM, MISO, and ISO–NE either support the compliance deadline or believe that they can meet the compliance deadline once a Final Rule is published in the **Federal Register**.[279]

184. ISO–NE supports the implementation timeline for the shortage pricing proposal because it believes that its market already meets the NOPR proposal.[280] Similarly, ISO–NE states that it has already engaged its participants to discuss tariff changes to settle the real-time markets in five-minute intervals, and is therefore not concerned with the implementation timeline because it anticipates tariff changes will be filed with the Commission in mid-2016, to be effective in 2017.[281]

185. MISO states that it already has a project in progress to replace the current software systems that perform market and transmission settlements processing,[282] and it estimates that an additional eight months would be required to mitigate any issues related to the new software and complete development of the revised settlement system, allowing implementation by the fourth quarter of 2017.[283] MISO states that the Commission should allow each RTO/ISO to propose, in its compliance filing, what it believes is a reasonable implementation schedule.[284]

186. PJM asserts that it can make a compliance filing four months after the date of the Final Rule, but is concerned that insufficient time was suggested for implementation.[285] PJM hopes to complete an evaluation of what changes are needed in its settlement system around April 2016, but, depending upon on the outcome of that analysis, it estimates that revising the settlement process will require between fifteen to thirty-eight months.[286] PJM also states that, though it opposes the shortage pricing proposal, if the Commission orders some version of shortage pricing reform, the Commission should consider simultaneous implementation of shortage pricing with the settlement interval proposal.[287]

187. CAISO also states that, depending upon the specifics of the Final Rule, extra time may be necessary for a complete compliance filing.[288]

b. Comments Urging Flexibility in Implementation

188. Several commenters urge flexibility in the implementation timelines.[289] The New Jersey Board concurs with PJM that, given the technical uncertainties involved, the Commission, in the Final Rule, should provide flexibility in the implementation timeline.[290] Duke states that the RTOs/ISOs should determine the implementation timeline after first exploring system design options, cost impacts to market participants, and approaches to reduce cost impacts.[291] EEI and APPA and NRECA contend that not only is a flexible implementation timeline necessary, but RTOs/ISOs should also be encouraged to work with market participants to ensure they have the necessary systems and metering in place in advance.[292]

189. NEPOOL, Golden Spread, and TAPS echo the statements of EEI,

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[275] Concerned Cooperatives Comments at 18–25; ELCON Comments at 2; PG&E Comments at 2.

[276] Concerned Cooperatives Comments at 15.

[277] NOPR, FERC Stats. & Regs. ¶ 32,710 at PP 38, 54–55.

[278] ISO/RTO Council Comments at 3.

[279] PJM Comments at 7; MISO Comments at 13; ISO–NE Comments at 1.

[280] ISO–NE Comments at 3.

[281] ISO–NE Comments at 2. "ISO–NE plans to implement five-minute settlement of real-time reserves as part of the implementation of five-minute settlement of real-time energy transactions, which is currently being discussed with stakeholders." *Id.* at 3.

[282] MISO Comments at 3.

[283] MISO Comments at 6.

[284] MISO Comments at 12.

[285] PJM Comments at 7.

[286] PJM Comments at 3–4.

[287] PJM addresses its objections to the shortage pricing proposals in the PJM and SPP Comments.

[288] CAISO Comments at 25. CAISO has asked for certain clarifications as part of its comments, and states that if the Commission does not make the necessary clarifications, CAISO will need extra time to consider what changes would need to be made to its systems, and to develop implementing tariff language along with the supporting filing. *Id.*

[289] ISO/RTO Council Comments at 3; New Jersey Board Comments at 3; PJM Comments at 4; EEI Comments at 8; NEPOOL Comments at 1; Golden Spread Comments at 7–8.

[290] New Jersey Board Comments at 3 (citing PJM Comments at 4).

[291] Duke Comments at 6.

[292] EEI Comments at 8; APPA and NRECA Comments at 4–5.

contending that implementation should account for specific differences between the RTOs/ISOs instead of imposing a rigid standard.[293]

190. Although TAPS argues against the proposed shortage pricing rule, it states that if the rule is adopted, then needed administrative shortage pricing level modifications should become effective when other shortage pricing modifications become effective.[294] Golden Spread also identifies issues it believes need to be addressed before the proposed shortage pricing requirement can be properly implemented in SPP.[295]

c. Compliance Filing Deadline

191. Some commenters commented on the amount of time allowed to submit a compliance filing. With regard to the settlement interval proposal, Concerned Cooperatives state that because it could take over a year to determine what market rules may need modification and to subsequently implement those changes, the Commission should require a compliance filing after one year so that RTOs/ISOs can discuss implementation issues with stakeholders.[296] TAPS states that the four-month compliance deadline proposed in the NOPR is too short because a rule adjusting shortage pricing triggers needs to be accompanied by an adjustment to shortage pricing levels.[297]

d. Implementation Deadline

192. PSEG states that, in markets where the current equipment can be utilized, the twelve-month implementation timeline proposed by the NOPR would be reasonable.[298] However, PSEG notes that the Commission must take into account the time it will take the individual RTOs/ISOs to implement computer system changes.[299] Several commenters assert that the timelines for implementation mentioned in the NOPR may be too short.

193. ODEC asserts that, instead of requiring implementation within twelve months of the compliance filings, if the Commission determines PJM must settle resources at the same interval those resources are dispatched, then the Commission should require each RTO/ISO to submit a proposed plan for compliance and implementation of the Final Rule.[300]

194. Exelon maintains that the implementation period for the five-minute settlement interval proposal should be 18 months because of the equipment changes that will be necessary for generators in the RTOs/ISOs that do not currently use five-minute pricing.[301]

195. Ameren argues the timeline proposed in the NOPR is too short and could potentially increase both costs and risks to the detriment of their customers.[302] As for the settlement interval proposal, Ameren states that the implementation timeline developed from its internal assessment is at least 24 months to 29 months, with a possible implementation date of June 1, 2018 if a Final Rule is issued in early 2016.[303]

196. Dominion and IPL point out that implementation timing and specifics for market participants will depend upon when the RTOs/ISOs finalize their own implementation details, and it argues that the proposed twelve-month implementation period for settlement interval reforms does not appropriately take this factor into account.[304]

197. DTE states that it would need a minimum of eighteen months and "several million dollars" to implement necessary changes to its settlement system,[305] and Duke is concerned that twelve months will not be enough time.[306] DTE and Duke emphasize that it is essential for the Commission to encourage RTOs/ISOs to work with stakeholders and market participants in order to facilitate the most cost-effective and timely implementation.[307] Commenting on the shortage pricing proposal, Concerned Cooperatives, who also contend stakeholders need to work cooperatively with RTOs/ISOs, assert that the implementation timeline is not long enough, and that the Commission should allow at least a year for the RTOs/ISOs to vet the shortage pricing implementation details with their stakeholders.[308]

198. APPA and NRECA request that RTOs/ISOs ensure all market participants either have the necessary metering and billing systems in place or have sufficient time to add required systems.[309]

199. Only one entity, Direct Energy, requested an indefinite delay of implementation: Specifically, for the five-minute settlement proposal, arguing that the underlying technology of many supply resources is not advanced enough to ensure the efficiency the Commission states it seeks in the NOPR.[310]

e. Simultaneous Implementation

200. Some commenters argue that the Commission should synchronize implementation of the shortage pricing reform with the settlement interval proposal due to their interrelated nature.[311]

f. Costs

201. In the NOPR, the Commission noted that while adopting the proposed reforms might provide significant benefits, implementing and modifying settlement systems can be complex and costly.[312] Various commenters provided settlement implementation cost estimates: PJM ($3 to $5.6 million),[313] Ameren ($3 million, plus an additional $13 to $20 million if the settlement interval proposal is applied to load),[314] Duke ($1 to $3.25 million, plus an additional $4 million if the settlement interval proposal is applied to load),[315] and Concerned Cooperatives ($1.5 to $2 million capital costs and $300,000 to $600,000 annual costs).[316]

202. While the NOPR did not propose that a cost-benefit analysis must be performed in conjunction with the proposed reforms, some commenters discuss whether a formal cost-benefit analysis is necessary prior to implementation of the proposals. APPA and NRECA, Concerned Cooperatives, Ameren, and IPL claim that a cost-benefit analysis is necessary before implementation.[317] IPL asserts this

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[293] NEPOOL Comments at 5; Golden Spread Comments at 7–8; TAPS Comments at 14–15.

[294] TAPS Comments at 13.

[295] Golden Spread Comments at 8–10.

[296] Concerned Cooperatives Comments at 12.

[297] TAPS Comments at 14.

[298] PSEG Comments at 8.

[299] PSEG Comments at 15; Inertia Power Comments at 9.

[300] ODEC Comments at 5.

[301] Exelon Comments at 5.

[302] Ameren Comments at 6.

[303] Ameren Comments at 6–7. Ameren also suggests "aligning the implementation of a final rule with the beginning of the MISO Planning Year, *i.e.* June 1, in order to facilitate a more seamless transition." *Id.*

[304] Dominion Comments at 2; IPL Comments at 2–3.

[305] DTE Comments at 4–5. DTE explains that these changes would include, among other things, evaluating its meters and computer systems, as well as re-evaluating many of its current contracts. *Id.*

[306] Duke Comments at 6–7; DTE Comments at 4–5. DTE explains that these changes would include, among other things, evaluating its meters and computer systems, as well as re-evaluating many of its current contracts. *Id.*

[307] DTE Comments at 5; Duke Comments at 6–7.

[308] Concerned Cooperatives Comments at 26–27.

[309] APPA and NRECA Comments at 4–5.

[310] Direct Energy Comments at 6.

[311] PJM Comments at 10; EEI Comments at 10–11; DTE Comments at 6; EPSA Comments at 8; PSEG Comments at 15–16; Inertia Power and DC Energy Comments at 8–9.

[312] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 60.

[313] PJM Comments at 3–4.

[314] Ameren Comments at 5–6.

[315] Duke Comments at 6.

[316] Concerned Cooperatives Comments at 9.

[317] APPA and NRECA Comments at 4–5; Concerned Cooperatives Comments at 12; Ameren Comments at 4; IPL Comments at 2.

analysis will prove that market benefits will be small in comparison to the costs of implementation.[318] Conversely, EPSA and the PJM Market Monitor state that they should not be required to do a cost-benefit analysis (specifically in reference to sub-hourly pricing) because it would be too difficult to accurately measure or approximate the potential long-term benefits.[319]

203. Some commenters opine on how they perceive the costs relate to the benefits of the proposed reforms. Duke expresses concerns that the costs of aligning dispatch and settlement intervals will exceed the benefits. Duke acknowledges that the potential impact of these reforms is not currently knowable, given that MISO and PJM have not proposed new market rules and system changes.[320] However, Duke states that if RTOs/ISOs determine that costs associated with the proposed reform will not exceed the benefits, stakeholder discussions could involve software system changes and relevant costs and impacts on market participants.[321] In contrast, Inertia Power states that, although the long-term benefits are not quantifiable, the direct savings to consumers and market participants will warrant the costs. Inertia Power suggests that the Commission should consider the "immeasurable cost of muted price signals" when comparing costs to benefits.[322]

3. Commission Determination

204. Because the reforms required in this Final Rule are targeted and specific, we believe RTOs/ISOs will have sufficient time to develop and file tariff changes to adopt these limited reforms, contrary to the concerns of commenters such as Concerned Cooperatives and TAPS. In the NOPR, the Commission recognized that implementation of the settlement reform could take up to a year after the compliance filings were submitted.[323] With regard to shortage pricing, any revisions an RTO/ISO may propose to shortage pricing levels (which are not required by this Final Rule) must be filed under section 205 and could be submitted prior to the actual implementation of the shortage pricing provisions of this Final Rule, thereby permitting stakeholders and the RTO/ISO additional time to work through the implementation details.

205. Of the entities required to submit a compliance filing, PJM, MISO, and ISO–NE either support the compliance deadline or believe that they can meet the compliance deadline once a Final Rule is published in the **Federal Register**. Further, neither SPP nor NYISO submitted comments opposing the compliance deadline. CAISO expressed concern about its ability to submit a compliance filing within 120 days of the effective date of this Final Rule. We believe that, with the various clarifications provided in this Final Rule, CAISO should be able to submit a compliance filing within four months of the effective date of the Final Rule. Accordingly, we adopt the proposal in the NOPR and require each RTO/ISO to submit, within 120 days of the effective date of this Final Rule, a compliance filing that includes tariff changes that adopt the requirements in this Final Rule, or demonstrates how the RTO/ISO already complies. We will allow a further 12 months from the compliance filing date for the tariff changes implementing reforms to settlement intervals to be effective, and 120 days from that same compliance filing date for the tariff changes implementing shortage pricing reforms to be effective.[324]

206. As previously noted, comments on the implementation schedule focused on two areas: (1) Whether the Commission provided enough time to implement the settlement reform proposal; and (2) whether the Commission should extend implementation of the shortage pricing reform proposal to allow for simultaneous implementation of shortage pricing with settlement reform. Based upon the comments received, we retain the current implementation schedule, but will consider requests for extensions of time to extend the implementation dates when the RTOs/ISOs submit their compliance filings. The RTOs/ISOs will have had 120 days as they prepare their compliance filings to assess the feasibility of implementing the reforms set forth in this Final Rule. It is premature at this time to extend the implementation timelines when affected parties are only just starting to analyze what actions they must take in order to implement the requirements of the Final Rule.

207. Moreover, when the RTOs/ISOs submit their respective compliance filings, we will consider whether it is appropriate to permit the RTO/ISO to synchronize implementation of shortage pricing with the settlement interval based upon the facts presented at that time. We expect that any RTO/ISO seeking to synchronize shortage pricing with the settlement interval will set forth compelling reasons as to why it is necessary based upon the unique nature of the RTO/ISO.

208. We will not dictate how RTOs/ISOs must implement the reforms set forth in the Final Rule from a technical perspective. Nevertheless, we recommend that wherever possible, the RTO/ISO should consider using existing metering equipment and current data collection processes, such as the process currently being explored by PJM.[325]

209. With regard to the comments concerning the costs of implementing the NOPR proposals, we find that some of these costs appear to be overstated, taken as a whole. For example, PJM's use of its state estimator and telemetry may reduce, if not eliminate, the need for new five-minute revenue quality meters; and it is unclear, in the case of the Concerned Cooperatives, why costs equal to several more full-time employees would need to be incurred on an annual basis as a result of the NOPR reform. In any event, we find that the value of the benefits of more accurate pricing under the proposed rule described in the NOPR, as recognized by the vast majority of commenters in this proceeding, and the net present value of the future increases in market surplus, although difficult to quantify with precision, are likely to outweigh any one-time implementation costs.

210. We reject the proposal to require RTOs/ISOs to conduct a cost-benefit analysis before implementing the settlement reform.[326] The Commission has not previously conducted such analyses when it has considered whether to require various market reforms.[327] Also, since many of the expected benefits will occur in the long-run due to changes in marginal investments and enhancements resulting from other price formation reforms, there is limited ability to quantify the short-run benefits before adopting these reforms.[328] We agree with the PJM Market Monitor's assertion that, while the costs of implementation

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[318] IPL Comments at 2.

[319] EPSA Comments, Pope Aff. at 13–14; PJM Market Monitor Comments at 2–3.

[320] Duke Comments at 6.

[321] Duke Comments at 5.

[322] Inertia Power Comments at 7.

[323] NOPR, FERC Stats. & Regs. ¶ 32,710 at P 55.

[324] The Commission has followed a similar approach with the timelines for compliance and implementation in the past. *See, e.g.*, Order No. 755, FERC Stats. & Regs. ¶ 31,324 at P 201, *reh'g denied*, Order No. 755–A, 138 FERC ¶ 61,123.

[325] PJM Comments at 3.

[326] APPA and NRECA Comments at 4.

[327] *Cf.* Order No. 719–A, FERC Stats. & Regs. ¶ 31,292 at P 179 ("For instance, although we believe that cost-benefit analyses can be useful in analyzing new projects, we are unconvinced that the Commission should mandate cost-benefit analyses in all circumstances where an RTO or ISO engages in a major initiative").

[328] EPSA Comments, Pope Aff. at 13–14.

may be approximated, calculating the efficiency benefits of implementing five-minute settlements is effectively impossible.[329]

D. Requests Beyond the Scope of This Proceeding

1. Comments

211. Commenters raised issues that are not discussed above and that are outside of the scope of this rulemaking. EPSA states that the Commission and RTOs/ISOs must move expeditiously on the reforms proposed in the NOPR as well as others identified in the price formation proceeding that encourage economically efficient decisions about resource entry and exit.[330]

212. PJM Power Providers and Exelon urge the Commission to focus on reducing uplift and remedying its causes as well as market power mitigation, operator actions, and other issues.[331] PJM Power Providers, Exelon, EPSA, and NGSA also encourage Commission action on reforming the energy offer cap.[332]

213. ELCON, Westar, TAPS, and Inertia Power and DC Energy recognize the interconnected nature of the issues in the price formation proceeding. ELCON urges the Commission to consolidate any additional price formation proposals into a single NOPR.[333] Westar states that the Commission should consider the NOPR in conjunction with other items identified in the price formation proceedings.[334] TAPS states that RTOs/ISOs should have the flexibility to comply with all price formation rulemakings in a way that coordinates implementation and reduces the possibility of overlapping modifications of software and hardware.[335] Inertia Power and DC Energy asks the Commission to be mindful of other system benefits that may result from the required software and hardware upgrades in the RTO/ISOs.[336]

214. EEI and EPSA reiterate their prior comments regarding common principles that should guide the discussion of price formation: (1) Dispatch-based pricing; (2) efficient commitment that will provide accurate day-ahead and real-time price signals; and (3) transparency with regard to out-of-market actions and payments.[337] EEI further states that the Commission should consider issues related to improving the transparency of LMPs by addressing the treatment of start-up and no-load costs, and operator actions that result in out-of-market payments.[338]

215. Westar requests that the Commission encourage RTOs/ISOs to clarify what costs may constitute marginal costs.[339] Additionally, XO Energy lists many benefits of a day-ahead transmission product, and recommends the implementation of such a product across all RTOs/ISOs.[340]

216. Financial Marketers Coalition and XO Energy assert that while the NOPR addresses settlement intervals for generation (supply), similar reforms are needed for the intervals in which load is forecasted, bid and settled in order to eliminate the mismatch between generation and load.[341]

217. Entergy Nuclear Power Marketing and NEI state that although the reforms proposed in the NOPR will improve price formation for resources operating in real-time, they will not improve the outlook for baseload resources such as nuclear plants typically fully committed in the day-ahead market.[342]

218. NEI recommends various changes to price formation to better ensure that the market clearing price reflects all of the costs associated with reliably providing service to the market.[343]

219. With respect to other issues, DTE requests clarification from the Commission that market participants will not have to change the manner in which they currently net purchases and sales for purposes of FERC Form No. 1.[344] The SPP Market Monitor raises look-ahead modeling concerns.[345] Powerex has concerns regarding steps CAISO takes to minimize the occurrence of shortages (as opposed to when shortage pricing occurs)[346] and Public Interest Organizations have a concern regarding possible barriers to the participation of demand response in RTO/ISO markets.[347]

220. Referencing the NOPR's discussion of the role that look-ahead tools can play in mitigating seemingly artificial shortages, the SPP Market Monitor also requests the Commission clarify that look-ahead models incorporate administrative pricing in their least cost evaluation before choosing unit commitments to relieve shortages.[348]

221. Powerex argues that further Commission action is necessary to ensure that RTOs/ISOs refrain from using more general tariff provisions and non-tariff protocols, including out-of-market procurement and other operator interventions, to prevent shortage pricing from being triggered or otherwise prevent scarcity from being reflected in market prices.[349]

222. Dominion questions if the proposed settlement reforms require further consideration of the interactions between the day-ahead and real-time markets. Specifically, Dominion suggests that changes may be necessary to how the RTOs/ISOs calculate generator deviations in the real-time market from their day-ahead schedules.[350]

223. ESA requests that the Commission consider five-minute scheduling once it implements five-minute intervals to better access the greater operational flexibility of fast-ramping resources like energy storage.[351]

224. Powerex requests that the Commission require each RTO/ISO to: (1) Identify all out-of-market actions or procurement tools that it uses, or is authorized to use, to manage its system; and (2) propose tariff amendments to ensure that these actions are appropriately reflected in prices or, alternatively, demonstrate that its existing tariff provisions already achieve such a result.[352]

225. Appian Way states that the instant proposals encompassed by this NOPR are insufficient to ensure proper shortage pricing. Appian Way adds that some RTOs/ISOs will continue to have defective pricing unless and until the Commission requires them to establish pricing rules that ensure prices rise to scarcity levels when shortage conditions occur that require the RTO/ISO to call

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[329] PJM Market Monitor Comments at 2–3.

[330] EPSA Comments at 11.

[331] PJM Power Providers Comments at 7; Exelon Comments at 8.

[332] PJM Power Providers Comments at 6; EPSA Comments at 13–15; Exelon Comments at 8–9; NGSA Comments at 6 (citing NGSA Comments, Docket No. ER15–623–000 (filed Jan. 20, 2015)).

[333] ELCON Comments at 7.

[334] Westar Comments at 2–3.

[335] TAPS Comments at 6.

[336] Inertia Power and DC Energy Comments at 8.

[337] EEI Comments at 4–5 (citing EEI Comments, Docket No. AD14–14–000, at 2 (filed Mar. 6, 2015)); EPSA Comments at 12 and Att. B.

[338] EEI Comments at 6.

[339] Westar Comments at 3.

[340] XO Energy Comments at 2–3 (citing MISO, Virtual Spread Bid Proposal Stakeholder Workshop, at 10 (Nov. 18, 2013)).

[341] Financial Marketers Coalition Comments at 4–6; XO Energy Comments at 3–4.

[342] Entergy Nuclear Power Marketing Comments at 2–3; NEI Comments at 15.

[343] NEI Comments at 15–16.

[344] DTE Comments at 6.

[345] PSEG Comments at 14; SPP Market Monitor at 4–7; Westar Comments at 3.

[346] Powerex Comments at 9–13.

[347] Public Interest Organizations Comments at 4–5.

[348] SPP Market Monitor Comments at 7.

[349] Powerex Comments at 9.

[350] Dominion Comments at 3–4.

[351] ESA Comments at 4–5.

[352] Powerex Comments at 12–13.

demand response in order to serve load.[353]

226. Inertia Power and DC Energy state that when operating reserves and other ancillary services are priced "out of market," it prevents the triggering of shortage pricing and circumvents the intent of the NOPR.[354]

227. Potomac Economics states that the Commission's focus on shortage pricing should extend to transmission shortages.[355]

228. Public Interest Organizations state that if the Commission carries out the shortage pricing proposal as set forth in the NOPR, it should simultaneously ensure that demand-side resources can respond to those prices to reduce the potential for unjust and unreasonable rates.[356]

229. Mr. Lively maintains that shortages should be viewed as a continuum, not as a shortage versus non-shortage issue. Mr. Lively cites a paper he wrote that discusses using Area Control Error (ACE) in a pricing mechanism to adjust the nominal price of electricity to determine a settlement price.[357]

2. Commission Determination

230. We appreciate the concerns raised by numerous commenters requesting that the Commission undertake various initiatives, as set forth above. However, we find that the requested initiatives go beyond the scope of this rulemaking. Many of the issues raised by commenters may be relevant in other price formation proceedings,[358] but they go beyond the limited issues in this proceeding, which deals only with the settlement interval proposal and the trigger for shortage pricing. Accordingly, we will not address those issues here.

IV. Information Collection Statement

231. The Paperwork Reduction Act (PRA)[359] requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB's regulations,[360] in turn, require approval of certain information collection requirements imposed by agency rules. Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to these collection(s) of information unless the collection(s) of information display a valid OMB control number.

232. In this Final Rule, we are amending the Commission's regulations to improve the operation of organized wholesale electric power markets operated by RTOs and ISOs. We require that each RTO/ISO align settlement and dispatch intervals by: (1) Settling energy transactions in its real-time markets at the same time interval it dispatches energy; (2) settling operating reserves transactions in its real-time markets at the same time interval it prices operating reserves; and (3) settling intertie transactions in the same time interval it schedules intertie transactions. We also require that each RTO/ISO trigger shortage pricing for any interval that prices both energy and operating reserves in which a shortage of energy or operating reserves is indicated during the pricing of resources for that interval. The reforms required in this Final Rule require a one-time tariff filing due 120 days after the effective date of this Final Rule. With regard to those RTOs/ISOs that believe that they already comply with the reforms required here, they can demonstrate their compliance in their compliance filing. The Commission will submit the proposed reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.[361]

233. Although the Commission stated in the NOPR that it expects the adoption of the reforms proposed to provide significant benefits,[362] the Commission solicited comments on the accuracy of provided burden and cost estimates set forth in the NOPR and any suggested methods for minimizing the respondents' burdens, including the use of automated information techniques. Specifically, the Commission sought detailed comments on the potential cost and time necessary to implement aspects of the reforms proposed in the NOPR, including (1) hardware, software, and business processes changes; (2) increased data storage and validation; (3) changes to market participant metering or other equipment; and (4) processes for RTOs/ISOs to vet proposed changes amongst their stakeholders. The Commission also sought comment on whether changes in settlement systems would disrupt existing contractual relationships and, if so, what burdens this might impose and how the Commission should address any potential issues resulting from such disruption.

234. The Commission received responses regarding the costs of implementing the reforms described in the NOPR;[363] however we find that those costs do not fall under the definition of "burden" as defined by OMB's regulations.[364] Therefore, an analysis of those costs is not relevant to our analysis under the PRA.

Burden Estimate and Information Collection Costs: We believe that the burden estimates below are representative of the average burden on respondents. The estimated burden and cost[365] for the requirements contained in this Final Rule follow.[366]

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[353] Appian Way Comments at 2.

[354] Inertia Power Comments at 5–6.

[355] Potomac Economics Comments at 11.

[356] Public Interest Organizations Comments at 3–5.

[357] Mr. Lively Comments at 3–4 (filed Nov. 23, 2015).

[358] *See, e.g., Offer Caps in Markets Operated by Regional Transmission Organizations and Independent System Operators,* Notice of Proposed Rulemaking, 81 FR 5591 (Feb. 4, 2016), FERC Stats. & Regs. ¶ 32,714 (2016), *Price Formation in Energy and Ancillary Services Markets Operated by Regional Transmission Organizations and Independent System Operators,* 153 FERC ¶ 61,221 (2015).

[359] 44 U.S.C. 3501–3520 (2012).

[360] 5 CFR part 1320 (2015).

[361] 44 U.S.C. 3507(d).

[363] *See supra* PP 201–203.

[364] "Burden" is defined as "the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency, including . . . (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information; (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information; (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information. . . ." 5 CFR 1320.3(b)(1) (2015). We respond to comments regarding other costs not related to "burden" (such as hardware and software) in PP 209–210 above.

[365] The estimated hourly cost (salary plus benefits) provided in this section are based on the salary figures for May 2015 posted by the Bureau of Labor Statistics for the Utilities sector (available at *http://www.bls.gov/oes/current/naics2_22.htm#00-0000*) and scaled to reflect benefits using the relative importance of employer costs in employee compensation from December 2015 (released March 10, 2016 and available at *http://www.bls.gov/news.release/ecec.nr0.htm*). The hourly estimates for salary plus benefits are:

Legal (code 23–0000), $128.94

Computer and Mathematical (code 15–0000), $60.54

Information Security Analyst (code 15–1122), $57.99

Accountant and Auditor (code 13–2011), $53.78

Information and Record Clerk (code 43–4199), $37.69

Electrical Engineer (code 17–2071), $64.20

Economist (code 19–3011), $74.43

Computer and Information Systems Manager (code 11–3021), $91.63

Management (code 11–0000), $88.94

The average hourly cost (salary plus benefits), weighting all of these skill sets evenly, is $73.13. For the calculations here, the Commission rounds it to $73 per hour.

[366] The RTOs/ISOs (CAISO, ISO–NE., MISO, NYISO, PJM, and SPP) are required to comply with the reforms in this Final Rule. Three RTOs/ISOs

Continued

FERC 516D,[367] as implemented in final rule in RM15–24–000	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) × (2) = (3)	Average burden hours & cost per response (4)	Annual burden hours & total annual cost (3) × (4) = (5)
Tariff filings one-time in Year 1, for RTOs/ISOs that currently align real-time settlement with dispatch intervals.	3 RTOs or ISOs	1	3	80 hrs; $5,840	240 hrs; $17,520.
Tariff filings one-time in Year 1, for RTOs/ISOs that *do not* currently align real-time settlement with dispatch intervals.	3 RTOs or ISOs	1	3	160 hrs; 11,680	480 hrs; 35,040.
Total (one-time in Year 1)[368].	6		6		720 hrs.; 52,560.

Title: FERC–516D, Electric Rate Schedules and Tariff Filings in Docket RM15–24.

Action: A new information collection.

OMB Control No.: To Be Determined.

Respondents for This Rulemaking: RTOs and ISOs.

Frequency of Information: One-time during Year one.

Necessity of Information: The Federal Energy Regulatory Commission implements this rule to improve competitive wholesale electric markets in the RTO and ISO regions.

Internal Review: The Commission has reviewed the changes and has determined that such changes are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has specific, objective support for the burden estimates associated with the information collection requirements.

235. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], email: *DataClearance@ferc.gov,* Phone: (202) 502–8663, fax: (202) 273–0873. Comments concerning the collection of information and the associated burden estimate(s) may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. Due to security concerns, comments should be sent electronically to the following email address: *oira_submission@omb.eop.gov.* Comments submitted to OMB should refer to FERC–516D and OMB Control No. To Be Determined.

V. Environmental Analysis

236. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[369] We conclude that neither an Environmental Assessment nor an Environmental Impact Statement is required for this Final Rule under section 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts and regulations that affect rates, charges, classifications, and services.[370]

VI. Regulatory Flexibility Act

237. The Regulatory Flexibility Act of 1980 (RFA)[371] generally requires a description and analysis of rules that will have significant economic impact on a substantial number of small entities. The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected.

238. This rule applies to six RTOs/ISOs (all of which are transmission organizations). The three RTOs/ISOs that do not currently align real-time settlement with dispatch intervals will have to incur a one-time cost to upgrade their hardware and software. These enhancements will be needed to allow the RTOs/ISOs to process settlement data on a more granular level. That one-time cost (spread over Years 1 and 2) for hardware and software for each of those three RTOs/ISOs is estimated to be an average of $3 million (a total of $9 million for those three RTOs/ISOs). The average estimated burden cost (one-time in Year 1) to each of the RTOs/ISOs is $8,760 (total of $52,560 for all six RTOs/ISOs). Therefore the estimated total cost (burden, hardware, and software) over Years 1 and 2 for all six RTOs/ISOs is $9,052,560.

(ISO–NE., MISO, and PJM) currently do not align real-time settlement with dispatch intervals and thus likely would be burdened more by that aspect of the reforms in this Final Rule.

[367] The information collection requirements and related burden for the NOPR in Docket No. RM15–24 were submitted to OMB under FERC–516 (Electric Rate Schedules and Tariff Filings, OMB Control No. 1902–0096). Currently, there is an unrelated package (in Docket No. PL15–3) pending OMB review under FERC–516. Because only one item per OMB Control No. can be pending OMB review at a time, the reporting requirements in the Final Rule in RM15–24 are being submitted to OMB for review under FERC–516D (a temporary 'placeholder' collection number, OMB Control No. to be determined). Long-term, the staff expects to transfer administratively the requirements and burden of this final rule to FERC–516 (OMB Control No. 1902–0096) from FERC–516D.

[368] The burden costs (one-time in Year 1) consist of filing proposed tariff changes to the Commission within four months of the effective date of the Final Rule.

[369] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[370] 18 CFR 380.4(a)(15) (2015).

[371] 5 U.S.C. 601–612 (2012).

[372] The RFA definition of "small entity" refers to the definition provided in the Small Business Act,

239. The RTOs/ISOs, however, are not small entities, as defined by the RFA.[372] This is because the relevant threshold between small and large entities is 500 employees and the Commission understands that each RTO/ISO has more than 500 employees. Furthermore, because of their pivotal roles in wholesale electric power markets in their regions, none of the RTOs/ISOs meet the last criterion of the two-part RFA definition of a small entity: "Not dominant in its field of operation." As a result, we certify that the reforms required by this Final Rule would not have a significant economic impact on a substantial number of small entities.

VII. Document Availability

240. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

241. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

242. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VIII. Effective Date and Congressional Notification

243. These regulations are effective September 13, 2016. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

By the Commission.

Issued: June 16, 2016.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission amends part 35, chapter I, title 18, *Code of Federal Regulations,* as follows:

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Amend § 35.28 as follows:

■ a. Revise paragraph (g)(1)(iv)(A).

■ b. Add paragraph (g)(1)(vi).

§ 35.28 Non-discriminatory open access transmission tariff

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(g) * * *

(1) * * *

(iv) * * *

(A) Each Commission-approved independent system operator and regional transmission organization must modify its market rules to allow the market-clearing price during periods of operating reserve shortage to reach a level that rebalances supply and demand so as to maintain reliability while providing sufficient provisions for mitigating market power. Each Commission-approved independent system operator and regional transmission organization must trigger shortage pricing for any interval in which a shortage of energy or operating reserves is indicated during the pricing of resources for that interval.

* * * * *

(vi) *Settlement intervals.* Each Commission-approved independent system operator and regional transmission organization must settle energy transactions in its real-time markets at the same time interval it dispatches energy, must settle operating reserves transactions in its real-time markets at the same time interval it prices operating reserves, and must settle intertie transactions at the same time interval it schedules intertie transactions.

* * * * *

Note: The following appendix will not be published in the *Code of Federal Regulations.*

Appendix: List of Commenters

The following is a list of the entities that filed comments in this proceeding, along with the short name/acronym used in this Final Rule. Unless otherwise noted, all comments were submitted on November 30, 2015.

Comments

Short name/acronym	Commenter
AEMA	Advanced Energy Management Alliance.
Ameren	Ameren Services Company (on behalf of Ameren Illinois Company and Union Electric Company).
ANGA	America's Natural Gas Alliance.
APPA and NRECA	American Public Power Association and National Rural Electric Cooperative Association.
Appian Way	Appian Way Energy Partners.
CAISO	California Independent System Operator Corporation.
CEA	Canadian Electricity Association.
Concerned Cooperatives	Hoosier Energy Rural Electric Cooperative, Inc., Kansas Electric Power Cooperative, Inc., and North Carolina Electric Membership Corporation.
Delaware Commission	Delaware Public Service Commission.
Direct Energy	Direct Energy Business, LLC and Direct Energy Business Marketing, LLC.
Dominion	Dominion Resources Services, Inc.
DTE	DTE Electric Company.

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which defines a "small business concern" as a business that is independently owned and operated and that is not dominant in its field of operation. The Small Business Administration's regulations at 13 CFR 121.201 (2015) define the threshold for a small Electric Bulk Power Transmission and Control entity (NAICS code 221121) to be 500 employees. *See* 5 U.S.C. 601(3) (2012) (citing to section 3 of the Small Business Act, 15 U.S.C. 632 (2012)).

Short name/acronym	Commenter
Duke	Duke Energy Corporation, Duke Energy Progress, LLC, Duke Energy Carolinas, LLC, Duke Energy Kentucky, Inc., Duke Energy Indiana, Inc., and Duke Energy Ohio, Inc.
EDP Renewables	EDP Renewables North America LLC.
EEI	Edison Electric Institute.
ELCON	Electricity Consumers Resource Council.
ESA	Energy Storage Association.
EPSA	Electric Power Supply Association.
Entergy Nuclear Power Marketing	Entergy Nuclear Power Marketing, LLC.
Exelon	Exelon Corporation.
Financial Marketers Coalition	Financial Marketers Coalition.
Golden Spread	Golden Spread Electric Cooperative, Inc.
Inertia Power and DC Energy	Inertia Power, LP and DC Energy, LLC.
IPL	Indianapolis Power & Light Company.
ISO/RTO Council	ISO/RTO Council.
ISO–NE	ISO New England Inc.
Mr. Lively	Mark B. Lively, Utility Economic Engineers.
MISO	Midcontinent Independent System Operator, Inc.
NEPOOL	New England Power Pool Participants Committee.
NEI	Nuclear Energy Institute.
New Jersey Board	New Jersey Board of Public Utilities.
NGSA	Natural Gas Supply Association.
NYISO	New York Independent System Operator, Inc.
ODEC	Old Dominion Electric Cooperative.
Mr. Centolella	Paul Centolella and Associates, L.L.C.
PG&E	Pacific Gas & Electric Company.
PJM	PJM Interconnection, L.L.C.
PJM Market Monitor	Monitoring Analytics, LLC, Independent Market Monitor for PJM.
PJM Power Providers	PJM Power Providers Group.
Potomac Economics	Potomac Economics, Ltd.
Powerex	Powerex Corp.
PSEG	PSEG Companies (Public Service Electric and Gas Company, PSEG Power LLC, and PSEG Energy Resources & Trade LLC).
Public Interest Organizations	Acadia Center, Americans for a Clean Energy Grid, Climate + Energy Project, Great Plains Institute, Natural Resources Defense Council, Sierra Club, Sustainable FERC Project, Union of Concerned Scientists, and Wind on the Wires.
SCE	Southern California Edison Company.
SPP	Southwest Power Pool, Inc.
SPP Market Monitor	Southwest Power Pool, Inc. Independent Market Monitoring Unit.
TAPS	Transmission Access Policy Study Group.
Westar	Westar Energy, Inc.
XO Energy	XO Energy, LLC.

REPLY OR SUPPLEMENTAL COMMENTS

Short name/acronym	Commenter	Date submitted
Golden Spread	Golden Spread Electric Cooperative, Inc	December 14, 2015.
Direct Energy	Direct Energy Business, LLC and Direct Energy Business Marketing, LLC	March 4, 2016.

LATE COMMENTS

Short name/acronym	Commenter	Date submitted
New Jersey Board	New Jersey Board of Public Utilities	December 3, 2015.

[FR Doc. 2016–15196 Filed 6–29–16; 8:45 am]

BILLING CODE 6717–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 126 June 30, 2016

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310
Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–2016–N–0124 (Formerly Part of Docket No. FDA–1975–N–0012)]

RIN 0910–AF69

Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this proposed rule to amend the 1994 tentative final monograph or proposed rule (the 1994 TFM) for over-the-counter (OTC) antiseptic drug products. In this proposed rule, we are proposing to establish conditions under which OTC consumer antiseptic products intended for use without water (referred to throughout as consumer antiseptic rubs or consumer rubs) are generally recognized as safe and generally recognized as effective (GRAS/GRAE). In the 1994 TFM, certain antiseptic active ingredients were proposed as being GRAS for antiseptic rub use by consumers based on safety data evaluated by FDA as part of its ongoing review of OTC antiseptic drug products. However, in light of more recent scientific developments and changes in the use patterns of these products, we are now proposing that additional safety data are necessary to support the safety of antiseptic active ingredients for this use. We also are proposing that all consumer antiseptic rub active ingredients have in vitro data characterizing the ingredient's antimicrobial properties and in vivo clinical simulation studies showing that specified log reductions in the amount of certain bacteria are achieved using the ingredient.

DATES: Submit electronic or written comments by December 27, 2016. See section IX of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions"). We note however, that the OTC drug monograph process is a public process; and, the Agency intends to consider only non-confidential material that is submitted to the docket for this rulemaking or that is otherwise publicly available in evaluating if a relevant ingredient is GRAS/GRAE.

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–0124 for "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Anita Kumar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5445, Silver Spring, MD 20993, 301–796–1032.

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I. Executive Summary

A. Purpose of the Regulatory Action

FDA is proposing to amend the 1994 TFM for OTC antiseptic drug products that published in the **Federal Register** of June 17, 1994 (59 FR 31402). The 1994 TFM is part of FDA's ongoing rulemaking to evaluate the safety and effectiveness of OTC drug products marketed in the United States on or before May 1972 (OTC Drug Review).

FDA is proposing to establish new conditions under which active ingredients used in OTC consumer antiseptic products intended to be used without water are GRAS/GRAE based on FDA's reevaluation of the safety and effectiveness data requirements proposed in the 1994 TFM for what were then referred to as antiseptic hand washes (which included the products we refer to in this document as consumer antiseptic rubs or consumer rubs). We are conducting this reevaluation based on the comments received, input from subsequent public meetings, and our independent evaluation of other relevant scientific information we have identified and placed in the docket. This proposed rule applies to active ingredients used in consumer antiseptic rub products that are sometimes referred to as rubs, leave-on products, or hand "sanitizers," as well as to consumer antiseptic wipes. These products are intended to be used when soap and water are not available, and are left on and not rinsed off with water. We will refer to them here as consumer antiseptic rubs or consumer rubs. In separate rulemakings (78 FR 76444, December 17, 2013; 80 FR 25166, May 1, 2015), we proposed conditions under which OTC consumer antiseptic washes and OTC antiseptics intended for use by health care professionals in a hospital setting or other health care situation outside the hospital are GRAS/GRAE. Those antiseptic products are not addressed in this proposed rule.

B. Summary of the Major Provisions of the Regulatory Action in Question

We are proposing that additional safety and effectiveness data are necessary to support a GRAS/GRAE determination for OTC antiseptic rub active ingredients intended for use by consumers. The effectiveness data, the safety data, and the effect on the previously proposed classification of active ingredients are described briefly in this summary. Because no ingredients currently meet the criteria for a GRAS/GRAE determination in this proposed rule, this rulemaking does not specifically address requirements for anticipated final formulation testing (*i.e.*, testing the mixture of both active and inactive ingredients proposed for marketing) or labeling. Final formulation testing could potentially involve both efficacy testing and safety testing to determine absorption. It is anticipated that if a final rule includes any GRAS/GRAE ingredients, labeling will be addressed as part of the final rule and may include elements related to application volume and safety labeling for children, including a warning to keep out of reach of children. We anticipate that specific effectiveness claims in labeling will reflect the testing performed in support of these claims. Effectiveness testing using surrogate endpoints as described in this proposed rule is designed to support antibacterial claims.

C. Effectiveness

A determination that a drug product containing a particular active ingredient would be GRAE for a particular intended use requires consideration of the benefit-to-risk ratio for the drug under the specified conditions of use. New information on potential risks posed by the use of certain consumer antiseptic products, as well as input from the Nonprescription Drugs Advisory Committee (NDAC) that met in March 2005 (the March 2005 NDAC) and October 2005 (the October 2005 NDAC), has prompted us to reevaluate the data needed for classifying active ingredients used in consumer rubs as GRAE. The reevaluation of effectiveness will help to ensure that the level of effectiveness achieved is adequate to offset newly identified safety concerns (see new information described in the safety section of this executive summary). We continue to propose the use of surrogate endpoints (bacterial log reductions) as a demonstration of effectiveness for consumer antiseptic rubs combined with in vitro testing to characterize the antimicrobial activity of the ingredient. However, the log reductions required for the demonstration of effectiveness for consumer rubs have been revised based on the recommendations of the March 2005 and October 2005 NDAC meetings, comments received after the 1994 TFM, and other information we reviewed.

We have evaluated the available literature, the data, and other information that were submitted to the rulemaking on the effectiveness of consumer rub active ingredients, as well as the recommendations from the public meetings held by the Agency on antiseptics. We propose that the record contain additional log reduction data to demonstrate the effectiveness of consumer rub active ingredients. We are also asking for data and information to be submitted about the impact of product use factors (such as volume of product per application) on efficacy to help inform labeling and requirements for final formulation testing.

D. Safety

Several important scientific developments that affect the safety evaluation of consumer rub active ingredients have occurred since FDA's 1994 evaluation of the safety of these active ingredients under the OTC Drug Review. Improved analytical methods now exist that can detect and more accurately measure these active ingredients at lower levels in the bloodstream and tissue. Consequently, we now know that, at least for certain consumer antiseptic rub ingredients, systemic exposure is higher than previously thought (Refs. 1 through 5), and new information is available about the potential risks from systemic absorption and long-term exposure. These data are particularly important given the increased use of consumer antiseptic rubs since the publication of the 1994 TFM. New safety information also suggests that widespread antiseptic use could have an impact on the development of bacterial resistance. Currently, the significance of this new information is not known and we are unaware of any information that would lead us to conclude that any consumer antiseptic rub active ingredient is unsafe (other than those that we proposed to be Category II in the 1994 TFM). The benefits of any active ingredient will need to be weighed against its risks once both the effectiveness and safety have been better characterized to determine GRAS/GRAE status.

The previously proposed GRAS determinations were based on safety principles that have since evolved significantly because of advances in technology, development of new test methods, and experience with performing test methods. The standard battery of tests that were used to determine the safety of drugs has changed over time to incorporate improvements in safety testing. To ensure that consumer antiseptic rub active ingredients are GRAS, data that meet current safety standards are needed.

Based on these developments, we are now proposing that additional safety data are needed for each consumer antiseptic rub active ingredient to support a GRAS classification. The data described in this proposed rule are the minimum data necessary to establish the safety of antiseptic active ingredients used in consumer antiseptic rub products in light of the new safety information. Consumers may use antiseptic rubs on a daily, long-term (*i.e.*, chronic) basis. The data we propose, which are needed to demonstrate safety for all consumer antiseptic rub active ingredients, fall into two broad categories: (1) Human safety studies and (2) nonclinical safety studies. For one of the consumer antiseptic rub active ingredients (benzalkonium chloride), data to evaluate the development of antimicrobial resistance also is required to demonstrate its safety.

E. Active Ingredients

Three active ingredients are being evaluated for use as a consumer antiseptic rub in this proposed rule: Alcohol (ethanol or ethyl alcohol), isopropyl alcohol, and benzalkonium chloride (sometimes referred to as ADBAC). As part of this proposed rule, FDA evaluated new data submitted after publication of the 1994 TFM for each of these three ingredients.

In the 1994 TFM (59 FR 31402 at 31435), alcohol (60 to 95 percent) was proposed to be classified as GRAS/GRAE (59 FR 31402 at 31435 to 31436) for use as what was then called an antiseptic hand wash (a use which included both products intended to be rinsed off (washes) and those intended to be left on (rubs)). Isopropyl alcohol (70 to 91.3 percent) was proposed to be categorized in Category III in the 1994 TFM because of a lack of adequate effectiveness data for use as an antiseptic hand wash (59 FR 31402 at 31435 to 31436). However, we now propose that both alcohol and isopropyl alcohol need additional safety and effectiveness data to support a classification of GRAS/GRAE for consumer antiseptic rub use. Our detailed evaluation of the effectiveness and safety of the active ingredients for which data were submitted can be found in sections VII.A and VIII.D.

In the 1994 TFM, FDA categorized benzalkonium chloride in Category III because of a lack of adequate safety and effectiveness data for its use as an antiseptic hand wash (59 FR 31402 at 31435). We have evaluated safety data received in response to the 1994 TFM and the consumer antiseptic wash proposed rule published in the **Federal Register** of December 17, 2013 (78 FR 76444) (2013 Consumer Wash Proposed Rule (PR)) (see section VIII.D). In this proposed rule, we propose that benzalkonium chloride needs additional safety and effectiveness data to support a classification of GRAS/GRAE for consumer antiseptic rub use.

If we do not receive sufficient data to support monograph conditions for consumer antiseptic rub products containing these active ingredients, these active ingredients may not be included in the future OTC consumer antiseptic rub final monograph. Any consumer antiseptic rub product containing the active ingredients being considered under this rulemaking that are not included in a future final monograph could seek approval to market by submitting new drug applications (NDAs) under section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355). After a final monograph is established, NDA deviations might be submitted for these products in accordance with 21 CFR 330.11, limiting the scope of review necessary to obtain approval.

F. Costs and Benefits

The impact of the proposed rule on the OTC consumer antiseptic rub product industry will depend on the outcome of tests to determine whether three antiseptic ingredients—alcohol, isopropyl alcohol, and benzalkonium chloride—are GRAS/GRAE. It is possible that none, one, two, or all three of the ingredients will be determined to be GRAS/GRAE. We consider two extreme scenarios to capture the entire range of total costs: (1) All three ingredients are deemed to be GRAS/GRAE or (2) none of the ingredients is deemed to be GRAS/GRAE.

The range of estimated costs is wide because the number of products that would need to be reformulated and relabeled depends on whether or not an antiseptic ingredient is deemed to be GRAS/GRAE. A small number of products contain active ingredients which FDA has determined are not eligible for use in consumer antiseptic rubs and these products will need to be reformulated and relabeled (scenario 1). However, in scenario 2 (and intermediate scenarios), the resulting costs are higher because a greater number of products will need to be reformulated and relabeled as a result of tests failing to show GRAS/GRAE status.

The total upfront costs of the proposed regulation—which include the expenditures to reformulate and relabel products that contain nonmonograph ingredients—are estimated to range from $0.34 million to $1.02 million for scenario 1 and from $15.99 million to $47.09 million for scenario 2. Annualizing upfront costs over a 10-year period at a discount rate of 3% for scenario 1, the costs of the proposed rule are estimated to be between $0.04 million and $0.12 million per year; the corresponding estimated cost at a discount rate of 7% is between $0.05 million and $0.14 million per year. In scenario 2, none of the ingredients is determined to be GRAS/E and we expect that manufacturers will reformulate their products to be free of antiseptics and relabel them to reflect the change in ingredients. Annualizing upfront costs over a 10-year period at a discount rate of 3% for scenario 2, the costs of the proposed rule are estimated to be between $1.87 million and $5.52 million per year; the corresponding estimated cost at a discount rate of 7% is between $2.28 million and $6.70 million per year. We assume that health risk falls with reduced exposure to potentially unsafe or ineffective antiseptic ingredients in consumer antiseptic rubs. We estimate that the proposed rule will reduce exposure to potentially unsafe or ineffective antiseptic ingredients in consumer antiseptic rubs by between 110 and 67,272,847 pounds.[1]

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[1] As was the case with estimated costs, there is a great disparity in the estimated reductions in exposure to antiseptic ingredients. The lower bound (110 pounds) represents the estimated reduction in

Summary of costs and benefits of the proposed rule	Total reduction in antiseptic ingredient exposure (in pounds)	Total costs annualized over 10 years (in millions)	Total one-time costs (in millions)
Total	110 and 67,272,847	$0.04 to $5.52 (3%) $0.05 to $6.70 (7%)	$0.34 and $47.09.

II. Introduction

In the following sections, we provide a brief description of terminology used in the OTC Drug Review regulations and an overview of OTC topical antiseptic drug products, and then describe in more detail the OTC consumer antiseptic rubs that are the subject of this proposed rule.

A. Terminology Used in the OTC Drug Review Regulations

1. Proposed, Tentative Final, and Final Monographs

To conform to terminology used in the OTC Drug Review regulations (§ 330.10 (21 CFR 330.10)), the September 1974 advance notice of proposed rulemaking (39 FR 33103, September 13, 1974) (1974 ANPR) was designated as a "proposed monograph." Similarly, the notices of proposed rulemaking, which were published in the **Federal Register** of January 6, 1978 (43 FR 1210) (the 1978 TFM), and in the **Federal Register** of June 17, 1994 (59 FR 31402) (the 1994 TFM), were each designated as a "tentative final monograph" (see table 1 in section III.A). The present proposed rule, which is a proposal to amend the 1994 TFM with respect to consumer antiseptic rub drug products, is also designated as a "tentative final monograph."

2. Category I, II, and III Classifications

The OTC drug procedural regulations in § 330.10 use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required). Section 330.10 provides that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph (*i.e.*, a final rule or regulation). Therefore, this proposed rule (the tentative final monograph stage) retains the concepts of Categories I, II, and III.

At the final monograph stage, FDA does not use the terms "Category I," "Category II," and "Category III." In place of Category I, the term "monograph conditions" is used; in place of Categories II and III, the term "nonmonograph conditions" is used.

B. Topical Antiseptics

The OTC topical antimicrobial rulemaking has had a broad scope, encompassing drug products that may contain the same active ingredients, but that are labeled and marketed for different intended uses. In 1974, the Agency published an ANPR for topical antimicrobial products that encompassed products for both health care and consumer use. The 1974 ANPR covered seven different intended uses for these products: (1) Antimicrobial soap; (2) health care personnel hand wash; (3) patient preoperative skin preparation; (4) skin antiseptic; (5) skin wound cleanser; (6) skin wound protectant; and (7) surgical hand scrub (39 FR 33103 at 33140). FDA subsequently identified skin antiseptics, skin wound cleansers, and skin wound protectants as antiseptics used primarily by consumers for first aid use and referred to them collectively as "first aid antiseptics." We published a separate TFM covering the first aid antiseptics in the **Federal Register** of July 22, 1991 (56 FR 33644) (1991 First Aid TFM). Thus, first aid antiseptics are not discussed further in this document.

The four remaining categories of topical antimicrobials were addressed in the 1994 TFM. The 1994 TFM covered: (1) Antiseptic hand wash (*i.e.*, consumer hand wash); (2) health care personnel hand wash; (3) patient preoperative skin preparation; and (4) surgical hand scrub (59 FR 31402 at 31442). In the 1994 TFM, FDA also identified a new category of antiseptics for use by the food industry and requested relevant data and information (59 FR 31402 at 31440). Antiseptics for use by the food industry are not discussed further in this document.

In the 1974 ANPR, we distinguished antimicrobial soaps used by consumers from professional use antiseptics, such as health care personnel hand washes. (See section II.C about the term "antimicrobial soaps.") In contrast, in the 1994 TFM, we proposed that both antiseptic hand washes (*i.e.*, consumer antiseptic washes) and health care personnel hand washes should have the same effectiveness testing and performance criteria. In response to the 1994 TFM, we received submissions from the public arguing that consumer products serve a different purpose and should continue to be distinct from health care antiseptics. We agreed, and in the 2013 Consumer Wash PR and in the health care antiseptic proposed rule published in the **Federal Register** of May 1, 2015 (80 FR 25166) (2015 Health Care Antiseptic PR), our evaluation of OTC antiseptic drug products has been further subdivided into consumer antiseptics and health care antiseptics, which are used by health care professionals in a hospital setting or other health care situations outside the hospital. We believe that these categories are distinct based on the proposed-use setting, target population, and the fact that each setting presents a different level of risk for infection. For example, in health care settings, the patient population is generally more susceptible to infection than the general U.S. consumer population (*i.e.*, the population who use consumer antiseptic rubs or washes). Furthermore, the purpose of use is generally different; health care antiseptics are primarily used to protect the patient (rather than just the user), whereas consumer antiseptics are generally applied to protect the user. In the health care setting, the potential for spread of infection and the potential for serious outcomes of infection may be relatively higher than in the U.S. consumer setting. Therefore, the safety and effectiveness should be evaluated separately for each intended use to support a GRAS/GRAE determination.

As we did in the 2013 Consumer Wash PR, we refer to the group of products covered by this proposed rule as "consumer antiseptics." Consumer antiseptic drug products addressed by this proposal include consumer antiseptic hand rubs (commonly called hand sanitizers) and antiseptic wipes.

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exposure to ingredients which FDA has determined are not GRAS/GRAE for use in consumer antiseptic rubs and few products contain such GRAS/GRAE ingredients.

These products may be used by consumers for personal use on a frequent basis, even multiple times per day. These products do not include personal care products intended to be used with water, such as antibacterial soaps, hand washes, and body washes.

C. This Proposed Rule Covers Only Consumer Antiseptic Rubs

In this proposed rule, FDA proposes the establishment of a monograph for OTC consumer antiseptics that are intended for use as an antiseptic rub, but that are not identified as "first aid antiseptics" in the 1991 First Aid TFM. When the 1994 TFM was published, the term for daily consumer use antiseptics was changed to "antiseptic hand wash." In response to this change, we received comments that the term "antiseptic hand wash" did not include all of the consumer products on the market, such as hand rubs and body washes. Therefore, in this proposed rule, we use the term "consumer antiseptic," which is a broad term and meant to include all of the types of antiseptic products used on a frequent or daily basis by consumers. However, this proposed rule covers only consumer antiseptic rubs and does not include consumer antiseptic hand washes or body washes.

The 1994 TFM did not distinguish between products that we are now calling "antiseptic washes" and products we are now calling "antiseptic rubs." Washes are rinsed off with water, and include consumer hand washes and body washes, and health care personnel hand washes and surgical hand scrubs. Rubs are sometimes referred to as "leave-on products" and are not rinsed off after use. They are intended to be used when soap and water are not available. Consumer antiseptic rubs include "hand sanitizers" and wipes. The 1994 TFM also did not distinguish between consumer antiseptic washes and rubs, and health care hand washes and rubs. This proposed rule covers only consumer antiseptic rubs. Completion of the monograph for consumer antiseptic rubs and certain other monographs for the active ingredient triclosan are subject to a Consent Decree entered by the U.S. District Court for the Southern District of New York on November 21, 2013, in *Natural Resources Defense Council, Inc.* v. *United States Food and Drug Administration, et al.*, 10 Civ. 5690 (S.D.N.Y.).

D. Comment Period

Because of the complexity of this proposed rule, we are providing a comment period of 180 days. Moreover, new data or information may be submitted to the docket via *http://www.regulations.gov* (see **ADDRESSES**) within 12 months of publication, and comments on any new data or information may then be submitted to the docket for an additional 60 days (see § 330.10(a)(7)(iii) and (iv)). In addition, FDA will also consider requests to defer further rulemaking with respect to a specific active ingredient for use as a consumer antiseptic rub to allow the submission of new safety or effectiveness data to the record if these requests are submitted to the docket within the initial 180-day comment period. FDA will review all data and information submitted to the record in conjunction with all timely and complete requests to defer rulemaking. In assessing whether to defer further rulemaking for a particular active ingredient to allow for additional time for studies to generate new data and information, FDA will consider the data already in the docket, along with any information that is provided in any requests. FDA will determine whether the sum of the data, if submitted in a timely fashion, is likely to be adequate to provide all the data that are necessary to make a GRAS/GRAE determination.

We note that the OTC Drug Review is a public process and any data submitted is public. There is no requirement or expectation that more than one set of data will be submitted to the docket for a particular active ingredient, and it does not matter who submits the data. In addition, data and other information for a single active ingredient may be submitted by any interested party and not all data for an ingredient must be submitted by a single party.

III. Background

In this section, we describe the significant rulemakings and public meetings relevant to this proposed rule, and how we are responding to comments received in response to the 1994 TFM.

A. Significant Rulemakings Relevant to This Proposed Rule

A summary of the significant **Federal Register** publications relevant to this proposed rule is provided in table 1. Other publications relevant to this proposed rule are available at *http://www.regulations.gov* in FDA Docket No. 1975–N–0012.

TABLE 1—SIGNIFICANT RULEMAKING PUBLICATIONS RELATED TO CONSUMER ANTISEPTIC DRUG PRODUCTS [1]

Federal Register Notice	Information in notice
1974 ANPR (September 13, 1974, 39 FR 33103).	We published an ANPR to establish a monograph for OTC topical antimicrobial drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial I Drug Products (Antimicrobial I Panel or Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class.
1978 Antimicrobial TFM (January 6, 1978, 43 FR 1210).	We published our tentative conclusions and proposed effectiveness testing for the drug product categories evaluated by the Panel. The 1978 TFM reflects our evaluation of the recommendations of the Panel and comments and data submitted in response to the Panel's recommendations.
1982 Alcohol ANPR (May 21, 1982, 47 FR 22324).	We published an ANPR to establish a monograph for alcohol drug products for topical antimicrobial use, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class.
1991 First Aid TFM (July 22, 1991, 56 FR 33644).	We amended the 1978 TFM to establish a separate monograph for OTC first aid antiseptic products. In the 1991 First Aid TFM, we proposed that first aid antiseptic drug products be indicated for the prevention of skin infections in minor cuts, scrapes, and burns.
1994 Health Care Antiseptic TFM (June 17, 1994, 59 FR 31402).	We amended the 1978 TFM to establish a separate monograph for the group of products that were referred to as OTC topical health care antiseptic drug products. These antiseptics are generally intended for use by health care professionals. In that proposed rule, we also recognized the need for antibacterial personal cleansing products for consumers to help prevent cross-contamination from one person to another and proposed a new antiseptic category for consumer use: Antiseptic hand wash.

TABLE 1—SIGNIFICANT RULEMAKING PUBLICATIONS RELATED TO CONSUMER ANTISEPTIC DRUG PRODUCTS [1]—Continued

Federal Register Notice	Information in notice
2013 Consumer Antiseptic Wash TFM (December 17, 2013, 78 FR 76444).	We issued a proposed rule to amend the 1994 TFM and to establish data standards for determining whether OTC consumer antiseptic washes are GRAS/GRAE. In that proposed rule, we proposed that additional safety and effectiveness data are necessary to support the safety and effectiveness of consumer antiseptic wash active ingredients.
2015 Health Care Antiseptics TFM (May 1, 2015, 80 FR 25166).	We issued a proposed rule to amend the 1994 TFM and to establish data standards for determining whether OTC health care antiseptics are GRAS/GRAE. In that proposed rule, we proposed that additional safety and effectiveness data are necessary to support the safety and effectiveness of health care antiseptic active ingredients.

[1] The publications listed in table 1 can be found at the FDA's "Status of OTC Rulemakings" Web site available at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm070821.htm.* The publications dated after 1993 can also be found in the **Federal Register** at *https://www.federalregister.gov.*

B. Public Meetings Relevant to This Proposed Rule

In addition to the **Federal Register** publications listed in table 1, there have been four meetings of the NDAC and one public feedback meeting that are relevant to the discussion of consumer antiseptic rub safety and effectiveness. These meetings are summarized in table 2.

TABLE 2—RELEVANT PUBLIC MEETINGS

Date and type of meeting	Topic of discussion
January 1997 NDAC Meeting (Joint meeting with the Anti-Infective Drugs Advisory Committee) (January 6, 1997, 62 FR 764).	Antiseptic and antibiotic resistance in relation to an industry proposal for consumer and health care antiseptic effectiveness testing (Health Care Continuum Model) (Refs. 6, 7).
March 2005 NDAC Meeting (February 18, 2005, 70 FR 8376).	The use of surrogate endpoints and study design issues for the in vivo testing of health care antiseptics (Ref. 8).
October 2005 NDAC Meeting (September 15, 2005, 70 FR 54560).	Benefits and risks of consumer antiseptics. NDAC expressed concern about the pervasive use of consumer antiseptic washes where there are potential risks and no demonstrable benefit. To demonstrate a clinical benefit, NDAC recommended clinical outcome studies to show that antiseptic washes are superior to nonantibacterial soap and water (Ref. 9).
November 2008 Public Feedback Meeting	Demonstration of the effectiveness of consumer antiseptics (Ref. 10).
September 2014 NDAC Meeting (July 29, 2014, 79 FR 44042).	Safety testing framework for health care antiseptic active ingredients (Ref. 11).

C. Comments Received by FDA

In response to the 1994 TFM, FDA received approximately 160 comments from drug manufacturers, trade associations, academia, testing laboratories, consumers, health professionals, and law firms. In response to the 2013 Consumer Wash PR, we received safety data regarding benzalkonium chloride that is relevant to this ingredient's use in a consumer rub and these data are evaluated in section VIII.D.2. Copies of the comments received are on public display at *http://www.regulations.gov* (see **ADDRESSES**). Because only consumer antiseptic rubs are discussed in this proposed rule, only those comments and data received in response to the 1994 TFM that are related to consumer antiseptic rub active ingredients are addressed. We also received comments related to final formulation testing and labeling conditions proposed in the 1994 TFM. If in the future we determine that there are monograph consumer antiseptic rub active ingredients that are GRAS/GRAE, we will address these comments. We invite further comment on the final formulation testing and labeling conditions proposed in the 1994 TFM, particularly in light of the data proposed in this proposed rule as necessary to support a GRAS/GRAE determination. Comments that were received in response to the 1994 TFM regarding other intended uses of the active ingredients are addressed in the 2013 Consumer Wash PR (78 FR 76444), or the 2015 Health Care Antiseptic PR (80 FR 25166), or will be addressed in future documents related to those other uses.

This proposed rule constitutes FDA's evaluation of submissions made in response to the 1994 TFM to support the safety and effectiveness of OTC consumer antiseptic rub active ingredients (Ref. 12). We reviewed the available literature and data and the comments submitted to the rulemaking and are proposing that adequate data for a determination of safety and effectiveness are not yet available for the consumer antiseptic rub active ingredients.

IV. Active Ingredients With Insufficient Evidence of Eligibility for the OTC Drug Review

In this section of the proposed rule, we describe the requirements for eligibility for the OTC Drug Review and the ingredients submitted to the OTC Drug Review that lack adequate evidence of eligibility for evaluation as consumer antiseptic rub products.

A. Eligibility for the OTC Drug Review

An OTC drug is covered by the OTC Drug Review if its conditions of use existed in the OTC drug marketplace on or before May 11, 1972 (37 FR 9464) (Ref. 13).[2] Conditions of use include, among other things, active ingredient, dosage form and strength, route of administration, and specific OTC use or indication of the product (see § 330.14(a)). To determine eligibility for the OTC Drug Review, FDA typically must have actual product labeling or a facsimile of labeling that documents the conditions of marketing of a product prior to May 1972 (see § 330.10(a)(2)). FDA considers a drug that is ineligible for inclusion in the OTC monograph system to be a new drug that will require FDA approval through the NDA process. Ineligibility for use as a consumer antiseptic rub does not affect eligibility under any other OTC drug monograph.

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[2] Also, note that drugs initially marketed in the United States after the OTC Drug Review began in 1972 and drugs without any U.S. marketing experience can be considered in the OTC monograph system based on submission of a Time and Extent Application. (See § 330.14).

B. Eligibility of Certain Active Ingredients for the OTC Drug Review

The following list includes those active ingredients that were addressed in the 1994 TFM for use as an antiseptic hand wash or health care personnel hand wash, and which currently do not have adequate evidence of eligibility for evaluation under the OTC Drug Review for use in a consumer antiseptic rub. Our review of the labeling submitted to the Panel or to FDA at a later time did not identify evidence demonstrating eligibility for the following active ingredients:

- Benzethonium chloride
- Chloroxylenol
- Chlorhexidine gluconate[3]
- Cloflucarban
- Fluorosalan
- Hexachlorophene
- Hexylresorcinol
- Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
- Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
- Methylbenzethonium chloride
- Nonylphenoxypoly (ethyleneoxy) ethanoliodine
- Phenol (less than 1.5 percent)
- Phenol (greater than 1.5 percent)
- Poloxamer iodine complex
- Povidone-iodine 5 to 10 percent
- Secondary amyltricresols
- Sodium oxychlorosene
- Tribromsalan
- Triclocarban
- Triclosan
- Triple dye
- Undecoylium chloride iodine complex

Following the publication of the 1994 TFM, FDA received submissions for the first time requesting that the following compounds be added to the monograph (Refs. 14 through 20):

- Polyhexamethylene biguanide
- Benzalkonium cetyl phosphate
- Cetylpyridinium chloride
- Calicylic acid, sodium hypochlorite
- Tea tree oil
- Combination of potassium vegetable oil solution, phosphate sequestering agent, and triethanolamine

These compounds were not addressed in prior FDA documents related to the monograph and were not evaluated for antiseptic hand wash use by the Antimicrobial I Panel. The submissions received by the Agency to date do not include documentation demonstrating the eligibility of any of these compounds for inclusion in the topical antimicrobial monograph (Ref. 21). Because of their lack of eligibility, effectiveness and safety information that has been submitted to the rulemaking for these consumer antiseptic rub active ingredients are not discussed in this proposed rule for such use. However, if documentation of the type described in section IV.A is submitted, these active ingredients could be determined to be eligible for evaluation for use as a consumer antiseptic rub.

V. Ingredients Previously Proposed as Not Generally Recognized as Safe and Effective

FDA may determine that an active ingredient is not GRAS/GRAE for a given OTC use (*i.e.*, nonmonograph) because of lack of evidence of effectiveness, lack of evidence of safety, or both. In the 1994 TFM (59 FR 31402 at 31435), FDA proposed that the active ingredients fluorosalan, hexachlorophene, phenol (greater than 1.5 percent), and tribromsalan be found not GRAS/GRAE for the uses referred to in the 1994 TFM as antiseptic hand wash and health care personnel hand wash. None of these ingredients currently have adequate evidence of eligibility for use in a consumer antiseptic rub (see section IV.B). Consequently, effectiveness and safety information that has been submitted to the rulemaking for these consumer antiseptic rub active ingredients are not discussed in this proposed rule for such use. However, if documentation of the type described in section IV.A is submitted, these active ingredients could be determined to be eligible for evaluation for use as a consumer antiseptic rub.

VI. Summary of Proposed Classifications of OTC Consumer Antiseptic Rub Active Ingredients

Table 3 lists the OTC consumer antiseptic active ingredients eligible for evaluation under the OTC Drug Review for use in consumer rubs, the classification proposed in the 1994 TFM, and the classification being proposed in this rulemaking. For each active ingredient, data that have been submitted to the public docket (for the topical antimicrobial rulemaking) and evaluated by FDA and the description of data still lacking in the administrative record are described in detail in section VIII.

TABLE 3—CLASSIFICATION OF OTC CONSUMER ANTISEPTIC RUB ACTIVE INGREDIENTS IN THE 1994 TFM AND IN THIS PROPOSED RULE

Active ingredient	1994 TFM proposal[1]	This proposed rule
Alcohol 60 to 95 percent	I[2]	IIISE[3]
Isopropyl alcohol 70 to 91.3 percent	IIIE	IIISE
Benzalkonium chloride	IIISE	IIISE

[1] Because the 1994 TFM did not describe antiseptic hand washes and rubs separately, the 1994 TFM classification was for use as an antiseptic hand wash or health care antiseptic hand wash.

[2] "I" denotes a classification that an active ingredient has been shown to be safe and effective.

[3] "III" denotes a classification that additional data are needed. "S" denotes safety data needed. "E" denotes effectiveness data needed.

In the 1994 TFM, alcohol was classified as Category I, isopropyl alcohol was classified as Category IIIE, and benzalkonium chloride was classified as Category IIISE for use as an antiseptic hand wash or health care personnel hand wash. However, in this proposed rule, we are proposing to classify all three ingredients as Category IIISE for use as a consumer antiseptic rub because additional effectiveness and safety data are needed to classify each ingredient as GRAS/GRAE for this use.

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[3] Chlorhexidine gluconate 4 percent aqueous solution was found to be ineligible for inclusion in the monograph for any health care antiseptic use and was not included in the 1994 TFM (59 FR 31402 at 31413). We have not received any new information since the 1994 TFM demonstrating that this active ingredient is eligible for the topical antimicrobial monograph.

VII. Effectiveness (Generally Recognized as Effective) Determination

OTC regulations (§§ 330.10(a)(4)(ii) and 314.126(b) (21 CFR 330.10(a)(4)(ii) and 314.126(b))) define the standards for establishing that an OTC drug containing a particular active ingredient would be GRAE for its intended use. These regulations provide that supporting investigations must be adequate and well-controlled, and able to distinguish the effect of a drug from other influences such as a spontaneous change in the course of the disease, placebo effect, or biased observation. In general, such investigations include controls that are adequate to provide an assessment of drug effect, are adequate measures to minimize bias, and use adequate analytical methods to demonstrate effectiveness. For active ingredients being evaluated in the OTC Drug Review, this means that a demonstration of the contribution of the active ingredient to any effectiveness observed is required before an ingredient can be determined to be GRAE for OTC drug use.

In the 1994 TFM, we continued to apply a log reduction standard (a clinical simulation standard) for establishing effectiveness of consumer antiseptics originally proposed in the 1978 TFM (59 FR 31402 at 31412) for the proposed intended use of decreasing bacteria on the skin. The 1994 TFM log reduction standard for effectiveness is based on a surrogate endpoint (*i.e.*, number of bacteria removed from the skin), rather than a clinical outcome (*e.g.*, reduction in the number of infections). Although the test methods proposed in the 1994 TFM are intended to evaluate the effectiveness of antiseptic final formulations, this type of clinical simulation testing, when adequately controlled, can also be used to demonstrate that an active ingredient is GRAE for use in a consumer antiseptic rub product. As reflected by the recommendations of some public health agencies, FDA believes that consumer antiseptic rubs are generally used when hands are not visibly soiled, and soap and water are not readily available (Refs. 22, 23), for example, in settings such as school classrooms, childcare facilities, outdoors and various other public places (Ref. 24). However, as discussed in section VII.A, data from adequately controlled studies demonstrating the impact of consumer antiseptic rubs on infection rates are not available. In contrast to consumer washes, for which we are asking for clinical outcome data to support the benefit of these products, given the easily available alternative of washing with soap and water, there is no similar readily available alternative for consumer antiseptic rubs. A clinical outcome trial comparing the use of consumer antiseptic rubs to standard hand washing with soap and water has less applicability given that consumer antiseptic rubs are not generally used in situations in which soap and water are a readily available alternative. Therefore, we are currently recommending the use of clinical simulation studies because they are a practical means to assess the general effectiveness of consumer antiseptic rubs.

FDA has already relied on clinical simulation studies as a standard for evaluating effectiveness of hand antiseptic drug products approved under NDAs, which are proven to be an effective measure to lower the surgical site infection rate (Refs. 25 through 27). In addition, in our recently revised standards for evaluating the effectiveness of health care antiseptics published in May 2015 (80 FR 25166), we relied on clinical simulation studies based on the recommendations of the March 2005 NDAC. In contrast, in the 2013 Consumer Wash PR, we proposed an efficacy standard for consumer antiseptic washes that relies on clinical outcome trials, also based on NDAC recommendations. As noted previously, consumer antiseptic rub products are generally used when soap and water are not available, so consumers lack a readily available alternative. As such, we continue to propose a log reduction standard to demonstrate the general recognition of effectiveness for consumer antiseptic rubs in accordance with our standards for health care antiseptics, which contain the same active ingredients (*i.e.*, alcohol, isopropyl alcohol, and benzalkonium chloride). Details of our current proposed log reduction standard are outlined in section VII.B.

As discussed in section VII.A, we have evaluated the available effectiveness studies that were submitted to the OTC Drug Review or retrieved through the published literature to support the effectiveness for consumer antiseptic rubs using the log reduction criteria most recently proposed in the 1994 TFM (59 FR 31402 at 31448) (Refs. 28 and 29). We found that the available studies are not adequate to support a GRAE determination for any consumer antiseptic rub active ingredient under either the final formulation effectiveness testing criteria proposed in the 1994 TFM or under the GRAE criteria proposed in this proposed rule (see table 4).

We have also evaluated all the studies that were submitted to the OTC Drug Review and have searched the published literature for studies performed in consumer use settings that would provide the direct evidence of a clinical benefit from the use of consumer antiseptic rubs (Ref. 24). We are defining a clinical benefit here as a reduction in the number of infections in a population that uses the consumer antiseptic rubs. Although a definitive link between consumer antiseptic rubs and reduced infection rates has not been established, some public health agencies recommend the use of consumer antiseptic rubs when soap and water are not available (Refs. 22, 23).

A. Evaluation of Effectiveness Data

1. Clinical Simulation Studies

Most of the available data to support the effectiveness of consumer antiseptic rubs are based on clinical simulation studies, such as the ones described in the 1994 TFM (59 FR 31402 at 31444). The premise behind these studies as described in the 1994 TFM is that bacterial reductions translate to a reduced risk for infection. However, currently, there are no clinical data that demonstrate that the specific bacterial log reductions that we have relied upon as a demonstration of effectiveness lead to a specific reduction in infections. In our view, although a lower number of bacteria on hands may not directly translate into a reduced chance of infection, a reduced bacterial load does decrease the opportunity for infection when used in situations with no other options for hand cleansing. In this case, rather than comparing using consumer antiseptic rubs to hand washing with soap and water, we are comparing them to the alternative of not cleaning the hands. In addition, because we believe that the consumer antiseptic rubs are intended to provide immediate reduction of bacteria rather than a persistent benefit, we are proposing that log reductions be measured after a single bacterial challenge (see table 4), rather than after repeated contamination.

We have evaluated all clinical simulation studies that were submitted to the OTC Drug Review for evidence of the effectiveness of consumer antiseptic rub active ingredients under the log reduction criteria proposed in the 1994

TFM (59 FR 31402 at 31448) (Refs. 28 through 30). We also searched the published literature for clinical simulation studies that assess consumer antiseptic rubs' effectiveness using the log reduction criteria in the 1994 TFM (Refs. 28 and 29).

Overall, the studies used a variety of study designs, including nonstandard study designs. In some cases, data submitted to the OTC Drug Review were in the form of technical reports or published articles without any study details. There is insufficient information to evaluate the scientific merit of studies described in abstracts and technical reports. Most importantly, none of the evaluated studies were adequately controlled to demonstrate the contribution of the active ingredient to the effectiveness observed in the studies (43 FR 1210 at 1240) and, therefore, cannot be used to demonstrate that the active ingredient tested is GRAE.

In general, the evaluated studies also had at least one of the following deficiencies:

- Some studies that were described as using a standardized method (American Society for Testing and Materials (ASTM)[4] or 1994 TFM) varied from these methods without explanation or validation, and the majority of studies did not provide sufficient information about critical aspects of the study conduct.
- Many studies did not include appropriate controls; for example, most studies did not include a vehicle control or an active control (59 FR 31402 at 31448), and some studies that included an active control failed to use the control product according to its labeled directions (59 FR 31402 at 31448).
- Many studies did not provide sufficient detail concerning neutralizer use (43 FR 1210 at 1244) or validation of neutralizer effectiveness.
- The studies evaluated a small number of subjects (59 FR 31402 at 31449).
- Some studies did not sample all of the time points specified by the test method (59 FR 31402 at 31448).

FDA's detailed evaluation of the data is filed in Docket No. FDA–2016–N–0124, available at *http://www.regulations.gov.*

2. Clinical Outcome Studies

Although we are not currently proposing to require clinical outcome studies to support a GRAE determination in this proposed rule, FDA identified and evaluated clinical outcome studies from the published literature that could potentially provide evidence of effectiveness for the use of consumer antiseptic rubs (Ref. 24). In our view, clinical outcome studies evaluating the effectiveness of consumer rubs should be adequately controlled and include a placebo or negative control arm to show the effect of an active ingredient. Among the reviewed studies and published literature, there are only a few studies that use these specified parameters for evaluating the effectiveness of consumer antiseptic rubs (Ref. 25). Overall, most of the studies were confounded, underpowered, and/or not properly controlled.

Our detailed review of consumer hand rubs studies is available in Docket No. FDA–2016–N–0124 (Ref. 24). None of the alcohol-based hand rub studies demonstrating benefit were adequately controlled, thus they could not demonstrate the contribution of the antiseptic active ingredient to the observed clinical outcome of reduced infection rates. In general, the studies had the following design flaws:

- No comparison to vehicle.
- Small sample size.
- Lack of randomization, blinding, or both.
- Inadequate statistical power and, in some cases, a failure to analyze results for statistical significance.
- Inadequate description of methodology and data collection methods.
- Failure to observe and document hand rub application technique.

One clinical outcome study was identified that was randomized, blinded, and placebo-controlled and was well designed to evaluate the effectiveness of a particular antiseptic active ingredient (Ref. 31). Although it had several significant limitations that prevent it from being sufficient to establish effectiveness for use of the active ingredient in a consumer antiseptic rub, this study is the best among the available studies that evaluate the impact of consumer antiseptic rubs on infections.

This clinical outcome study performed in Sweden compared the effectiveness of a 70-percent alcohol-containing consumer antiseptic rub as an adjunct to hand washing with plain soap and water in childcare centers (Ref. 31). The study included 60 childcare centers (30 matched pairs) from 10 counties with a mean number of 50 children in each center. One childcare center from each matched pair was randomized to the intervention group, with the other serving as the control group. The intervention groups were provided instructions (verbal and written), and children and staff were asked to wash hands with plain soap and water, then rub with a 70-percent alcohol-containing consumer antiseptic rub. Control groups followed the same hand-washing protocol without the hand rub. The primary outcome was the rate of illness absenteeism. Parents were asked to report every episode when the child was absent from childcare because of illness, including the dates of absence, symptoms, and any medical treatment. There were 0.37 absences per 100 child hours in the control group, compared to 0.33 in the intervention group. The effect of the intervention was a 12-percent reduction in absenteeism. Based on the amount of hand rub used during the study, the estimated frequency of hand rub use by each child was two to six times per day. Although the study is well designed, there are several significant limitations, such as the following:

- No clinical or microbiological evaluation of illness.
- No specific infection was studied.
- Children kept home based on parent choice not addressed in the statistical analysis.
- Degree of illness and symptoms to keep child home varied among parents.

B. Current Standards: Studies Needed To Support a Generally Recognized as Effective Determination

In the 1994 TFM, we proposed that the effectiveness of antiseptic active ingredients could be supported by a combination of in vitro studies and in vivo clinical simulation testing as described in 21 CFR 333.470 (59 FR 31402 at 31444). In vitro studies are designed to demonstrate the product's spectrum and kinetics of antimicrobial activity, as well as the potential for the development of resistance associated with product use. In vivo test methods and evaluation criteria are based on the premise that bacterial reductions can be adequately demonstrated using tests that simulate conditions of actual use for OTC consumer antiseptic rub products and that those reductions are reflective of bacterial reductions that would be achieved during use. For the use of antiseptic rubs, some public health agencies (Ref. 22) recommend their use when soap and water are not available, and when there is no other reasonably available alternative for the consumer.

In addition to the standards described in section VII.B, the effectiveness of consumer antiseptic rubs can be affected by a variety of other factors related to product formulation and use. Section VII.C discusses these factors, which includes the number of times per day a product is used and the volume used in each use.

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[4] General information about ASTM can be found at *https://www.astm.org/.*

1. In Vitro Studies

The 1994 TFM proposed that the in vitro antimicrobial activity of an active ingredient could be demonstrated by a determination of the in vitro spectrum of antimicrobial activity, minimum inhibitory concentration (MIC) testing against 25 fresh clinical isolates and 25 laboratory strains, and time-kill testing against 23 laboratory strains (59 FR 31402 at 31444). Comments received in response to the 1994 TFM objected to the proposed in vitro testing requirements, stating that they were overly burdensome (Ref. 32). Submissions of in vitro data submitted to support the effectiveness of antiseptic active ingredients were far less extensive than what was proposed in the 1994 TFM (Ref. 33). Although we agree that the in vitro testing proposed in the 1994 TFM is not warranted for testing every final formulation of an antiseptic product that contains a GRAE ingredient, we believe that a GRAE determination for a consumer antiseptic active ingredient should be supported by adequate in vitro characterization of the antimicrobial activity of the ingredient. In addition, we now propose the option of assessing the minimum bactericidal concentration (MBC) as an alternative to testing the MIC to demonstrate the broad spectrum activity of the antiseptic. The ability of an antiseptic to kill microorganisms, rather than inhibit them, is more relevant for a topical product. Because GRAE status is a very broad determination that can apply to many different formulations of an active ingredient, we continue to propose that an evaluation of the spectrum and kinetics of antimicrobial activity of a consumer antiseptic rub active ingredient should be evaluated by the following testing:

- A determination of the in vitro spectrum of antimicrobial activity against potential pathogens (listed in this section) that may be encountered in consumer use settings where soap and water are not readily available. MIC or MBC testing of 25 representative clinical isolates and 25 reference (*e.g.*, American Type Culture Collection (ATCC)) strains of each of the microorganisms listed in this section.
- Time-kill testing of each of the following ATCC strains to assess how rapidly the antiseptic active ingredient produces its effect. The dilutions and time points tested should be relevant to the actual use pattern of the final product.

Gram-negative organisms.

○ *Haemophilus influenzae.*

○ *Bacteroides fragilis.*

○ *Enterobacter species.*

○ *Burkholderia cepacia* (ATCC 25416 and ATCC 25608).

○ *Escherichia coli* (ATCC 11775 and ATCC 25922).

○ *Klebsiella pneumoniae* (ATCC 13883 and ATCC 27736).

○ *Pseudomonas aeruginosa* (ATCC 15442 and ATCC 27853).

○ *Serratia marcescens* (ATCC 8100 and ATCC 14756).

○ *Campylobacter jejuni* (ATCC 33291 and ATCC 49943).

○ *Salmonella enterica Serovar Enteritidis* (ATCC 13076) and *Serovar Typhimurium* (ATCC 14028). Serovar refers to the subspecies classification of a group of microorganisms based on cell surface antigens.

○ *Shigella sonnei* (ATCC 9290 and ATCC 25931).

Gram-positive organisms.

○ *Enterococcus faecalis* (ATCC 19433 and ATCC 29212).

○ *Staphylococcus aureus* (ATCC 6538 and ATCC 29213) and methicillin-resistant *Staphylococcus aureus* (ATCC 33591 and ATCC 33592).

○ *Streptococcus pyogenes* (ATCC 14289 and ATCC 19615).

○ *Listeria monocytogenes* (ATCC 7644 and ATCC 19115).

○ *Streptococcus pneumoniae* (ATCC 6303 and ATCC 49619).

We propose that a consumer antiseptic rub active ingredient be considered bactericidal at the concentration and contact time that demonstrates a 3-$\log_{10}$ (99.9 percent) or greater reduction in bacterial viability for all the tested strains. This is the same performance criterion used by the Clinical and Laboratory Standards Institute (NCCLS, "Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline," NCCLS document M26–A, 1999).

Despite the fact that the in vitro data submitted to support the effectiveness of antiseptic active ingredients were far less extensive than proposed in the 1994 TFM, manufacturers may have data of this type on file from their own product development programs that have not been submitted to the rulemaking. Furthermore, published data may be available that would satisfy some or all these data requirement. Data from these in vitro studies, as well as data from the literature, may be used to inform labeling, in particular, if there are specific organisms for which an active ingredient does not have significant activity. It is anticipated that if data supporting use of a consumer antiseptic demonstrate lack of activity against a particular organism that requires labeling, that labeling would also be relevant in the health care setting.

2. In Vivo Studies

Based on the recommendations of the March 2005 NDAC meeting for health care antiseptic products, we continue to propose the use of bacterial log reductions as a means of demonstrating that consumer antiseptic rubs are GRAE (Ref. 8). The 1994 TFM also proposed final formulation testing for antiseptic hand washes (59 FR 31402 at 31448). We are not discussing the final formulation testing here because we are not proposing that any of the ingredients are GRAS/GRAE. Although, as previously noted, these proposed test methods are intended to evaluate the effectiveness of antiseptic final formulations, this type of clinical simulation testing when adequately controlled can also be used to demonstrate that an active ingredient is GRAE for use in a consumer antiseptic rub product. Based on our experience with the approval of NDA antiseptic products, and input from the March 2005 and October 2005 NDAC meetings, we recommend that the bacterial log reduction studies used to demonstrate that an active ingredient is GRAE for use in consumer antiseptic rub drug products include the following:

- A vehicle control to show the contribution of the active ingredient to effectiveness. The test product should be statistically superior to the vehicle control for the clinical simulation to be considered successful at showing that the test product is effective for use in consumer antiseptic rub products. Products with vehicles that have antimicrobial activity should consider using a negative control, such as saline, rather than a vehicle control.
- An active control to validate the study conduct, to assure that the expected results are produced. For the results to be valid, the active control should meet the appropriate log reduction criteria.
- A sample size large enough to show statistically significant differences from the results achieved using the vehicle, and meeting the threshold of at least a 70-percent success rate for the test product, including justification that the number of subjects tested is adequate for the test.
- Use of an appropriate neutralizer in all recovery media (*i.e.*, sampling solution, dilution fluid, and plating media) and a demonstration of neutralizer validation. The neutralizer is used to halt the antimicrobial activity of the antiseptic after product exposure so that a continued effect through subsequent dilution steps and culturing

thereby does not create inflated log reductions. The purpose of neutralizer validation is to show that the neutralizer used in the study is effective against the test and control products, and that it is not toxic to the test microorganisms. If a test product can be neutralized through dilution, this should be demonstrated in the neutralizer validation study.

- An analysis of the proportion of subjects who meet the log reduction criteria based on a two-sided statistical test for superiority to vehicle and a 95-percent confidence interval approach.

To establish that a particular active ingredient is GRAE for use in consumer antiseptic rubs, clinical simulation studies using the parameters described in this section should be evaluated using log reduction criteria similar to those proposed in the 1994 TFM (59 FR 31402 at 31448). Our current criteria are laid out in table 4. We have revised the log reduction criteria proposed for consumer antiseptic rubs based on the recommendations of the March 2005 NDAC and comments to the 1994 TFM, which argued that the demonstration of a cumulative antiseptic effect for these products is unnecessary. We agree that the critical element of the effectiveness is that a product must be effective after the first application because that represents the way in which consumer antiseptic rub products are used (59 FR 31402 at 31442). For these reasons, log reduction criteria are proposed only for a single application of the test product rather than multiple applications. Given that we are no longer requiring a cumulative antiseptic effect, the log reduction criteria were revised to reflect this single application and fall between the log reductions previously proposed for the first and last applications. The GRAE criteria proposed for consumer antiseptic rubs are based on log reductions achieved by antiseptics as shown in the published literature (Refs. 28 and 29) as well as those evaluated under the NDA process. Table 4 shows the log reductions that we would expect an effective consumer antiseptic rub active ingredient to meet to show that it is GRAE.

TABLE 4—CLINICAL SIMULATION TESTING BACTERIAL LOG REDUCTION EFFECTIVENESS CRITERIA IN THIS PROPOSED RULE AND IN THE 1994 TFM

Indication	1994 TFM	This proposed rule
Antiseptic hand wash/Consumer antiseptic rub.	(1) Reduction of 2 $\log_{10}$ on each hand within 5 minutes after the first wash and (2) Reduction of 3 $\log_{10}$ on each hand within 5 minutes after the tenth wash.	(1) Reduction of 2.5 $\log_{10}$ on each hand within 5 minutes after a single rub.

C. Impact of Application Parameters on Efficacy

Establishing GRAE status of active ingredients is one important aspect of ensuring the efficacy of OTC consumer antiseptic rub products. The standards for a GRAE determination for consumer antiseptic rubs have been described (see section VII.B). These standards will help determine final monograph active ingredients, as well as their permitted concentrations and the skin application time needed for the active ingredient to achieve adequate bacterial reduction. However, the efficacy of any particular final formulation of a consumer antiseptic rub appears to be affected by a variety of other factors related to product formulation and use.

These factors include the number of times per day a product is used and the volume used in each use. The number of times per day that a consumer antiseptic rub product is applied has been shown to be positively correlated with a reduction in illness-related absenteeism in a kindergarten school (Ref. 34). In addition, more specific measures of application parameters have been assessed. The volume of product applied and the skin coverage achieved by the applied volume appear to have an impact on efficacy of antiseptic rub products containing alcohol. In comparing five different application volumes of 70 percent ethanol gel with 85 percent ethanol gel and 70 percent ethanol foam, Kampf et al. (2013) demonstrated that the label recommended volume of 1.1 milliliters (mL) for the 70 percent ethanol products was not sufficient to achieve efficacy in in vivo efficacy testing according to ASTM methods (Ref. 35). The recommended application of 2 mL of 85 percent gel, as well as higher than recommended volumes of the 70 percent products, met efficacy criteria under ASTM E 2755–10 and ASTM E 1174–06 methods used in this study. In the same study, insufficient skin coverage with lower application volumes (1.1 mL) was suggested as the reason for failure to achieve efficacy. Failure to achieve effectiveness with the lower volume was based on observation of gaps in skin coverage after volunteers applied products containing fluorescent dye to their hands. In a similar study, Kampf (2008) assessed the efficacy and coverage of four hand rub products (foam or gel formulation unspecified) containing 85 percent, 62 percent, 61 percent, or 60 percent ethanol (Ref. 36). At an application volume of 2.4 mL, the 60 percent and 61 percent ethanol formulations failed to meet in vivo ASTM efficacy criteria while 2.4 mL application volumes of 62 percent and 85 percent ethanol formulations met the criteria. Application volumes of 3.6 mL met efficacy criteria for all ethanol concentrations tested (Ref. 36).

Given that the applied volume of product may have consequences for product efficacy, the factors that may affect application volume are of interest. Variability has been demonstrated in the output of both gel and foam antiseptic rub dispensers. Macinga et al. (2013) measured output from a single wall-mounted dispenser and among wall-dispensers from different manufacturers (Ref. 37). In dispensing five different gel formulations containing varying percentages of ethanol or isopropanol, dispensers from five different manufacturers had outputs that ranged from 0.9 to 1.3 mL per actuation. In dispensing three different foam formulations each containing 70 percent ethanol, foam dispensers from three different manufacturers ranged from 0.6 to 1.1 mL per actuation. Furthermore, the volume of product that individuals choose to apply may be affected, independent of labeled instruction, by factors such as the time it takes hands to dry after application. Kampf et al. (2010) assessed four foam formulations, each containing 62 percent ethanol, and found that the amount (weight) of foam applied was significantly correlated with the perceived drying time (Ref. 38). There is also evidence that final formulation affects efficacy. Different products containing the same concentration of active ingredient have been shown to perform differently when tested by in vivo bacterial reduction testing (ASTM 1174) (Ref. 39). One "novel" gel formulation and one "novel" foam formulation, each containing 70 percent ethanol, were both shown to be statistically superior after both 1 and 10 applications compared to two marketed formulations, one gel and one foam, both containing 70 percent ethanol. All formulations were applied in equal volumes. The two "novel" formulations also demonstrated some evidence of improved performance relative to a marketed gel containing 90 percent ethanol.

Understanding the impact of product-related parameters, such as formulation, dose applied, and application volume, to be used according to the labeling is imperative. We also need to understand the extent to which variability in product-related parameters must be reduced to ensure that products achieve the results expected based on their use of GRAE ingredients. Given the data demonstrating that efficacy varies with dose, application volume, and formulation, final formulation efficacy testing will be necessary for consumer antiseptic rub products in order to confirm effectiveness and label the product appropriately for use. However, because no ingredient has sufficient data to support GRAS/GRAE status in this rulemaking, we are not proposing specific final formulation testing or labeling at this time. Instead, we are requesting data to allow the assessment of the impact of various application parameters on efficacy and the interaction among them (*e.g.*, how does formulation affect application volume requirements) to inform final formulation testing and labeling requirements.

VIII. Safety (Generally Recognized as Safe) Determination

In the 1994 TFM, 11 active ingredients were proposed to be classified as GRAS for antiseptic hand wash use, which includes 2 active ingredients (alcohol and isopropyl alcohol) that are eligible for consumer antiseptic rub use (59 FR 31402 at 31435). As described in section II.C, consumer antiseptic hand rubs were not addressed separately from antiseptic hand washes in the 1994 TFM. There have since been a number of important scientific developments affecting our evaluation of the safety of the active ingredients in consumer antiseptic rubs, causing us to reassess the data necessary to support a GRAS determination. There is now new information regarding systemic exposure to antiseptic active ingredients (Refs. 1 through 5). The potential for widespread antiseptic use to promote the development of antibiotic-resistant bacteria also needs to be evaluated. Furthermore, additional experience with, and knowledge about, safety testing has led to improved testing methods. Improvements include study designs that are more capable of detecting potential safety risks. Based on our reassessment, we are proposing new GRAS data standards for consumer antiseptic rub active ingredients. To fully address these new safety concerns, additional safety data will be necessary to support a GRAS determination for all consumer antiseptic rub active ingredients.

Many of the safety considerations for consumer antiseptic rubs are based on FDA's view that the use of consumer antiseptic rubs is a "chronic" use as that term is defined by the International Council on Harmonisation (ICH).[5] As defined by the ICH, a use is considered chronic if the drug will be used for a period of at least 6 months over the user's lifetime, including repeated, intermittent use (Ref. 40). We believe that consumer antiseptic rubs are often used on a daily basis and sometimes repeatedly over the course of the day.

A. New Issues

Since the 1994 TFM was published, new data have become available indicating that systemic exposure to topical antiseptic active ingredients may be greater than previously thought. Systemic exposure refers to the presence of antiseptic active ingredients inside and throughout the body. Because of advances in technology, our ability to detect antiseptic active ingredients in body fluids such as serum and urine is greater than it was in 1994. For example, studies have shown detectable blood alcohol levels after use of alcohol-containing hand rubs (Refs. 1, 4, and 5). We believe that any consequences of this systemic exposure should be identified and assessed to support our risk-benefit analysis for consumer antiseptic use.

Given the frequent repeated use of consumer antiseptic rubs, systemic exposure may occur. Although some systemic exposure data exist for all three consumer antiseptic rub active ingredients, data on systemic absorption after maximal use are lacking. Currently, there is also a lack of data to assess the impact of important drug use factors that can influence systemic exposure such as dose, application frequency and method, duration of exposure, product formulation, skin condition, and age. Depending on the systemic absorption of the ingredient, variability in absorption anticipated between formulations, and the safety margin for toxic effects, final formulation safety testing for particular ingredients may be needed to assure that substantially different absorption that might significantly change the margin of safety is not anticipated for a new formulation. FDA does not address final formulation testing in this rulemaking because no ingredients have been proposed as GRAS/GRAE. However, FDA recently described final formulation safety testing for another class of OTC dermal products regulated under the OTC drug monograph (Ref. 41).

The evaluation of the safety of drug products involves correlating findings from animal toxicity studies to the level of drug exposure obtained from pharmacokinetic studies in animals and humans. Our administrative record lacks the data necessary to define a margin of safety for the potential chronic use of consumer antiseptic rub active ingredients. Thus, we are continuing to propose that both animal and human pharmacokinetic (PK) data are necessary for consumer antiseptic rub active ingredients. This information will help identify any potential safety concerns and help determine the safety margin for OTC human use.

One potential effect of systemic exposure to consumer antiseptic active ingredients that has come to our attention since publication of the 1994 TFM is data suggesting that some antiseptic active ingredients have hormonal effects. Ingredients in topical antiseptic products can cause alterations in the thyroid of neonatal and adolescent animals (Refs. 42 through 51). Hormonally active compounds have been shown to affect not only the exposed organism, but also subsequent generations (Ref. 52). These effects may not be related to direct deoxyribonucleic acid (DNA) mutation, but rather to alterations in factors that regulate gene expression (Ref. 53).

A hormonally active compound that causes reproductive system disruption in the fetus or infant may have effects that are not apparent until many years after initial exposure. There are also critical times in fetal development when a change in hormonal balance that would not cause any lasting effect in an adult could cause a permanent developmental abnormality in a child. For example, untreated hypothyroidism during pregnancy has been associated with cognitive impairment in the offspring (Refs. 54 through 56).

Because consumer antiseptic rubs are used chronically and are likely to be used by sensitive populations such as children and pregnant women, evaluation of the potential for chronic toxicity and effects on reproduction and development should be included in the safety assessment. The designs of general toxicity and reproductive/developmental studies are often sufficient to identify developmental effects that can be caused by hormonally active compounds through the use of currently accepted endpoints and standard good laboratory practice toxicology study designs. As followup in some cases, additional study endpoints may be needed to fully characterize the potential effects of drug exposure on the exposed individuals.

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[5] FDA is a member of the ICH Steering Committee, the governing body that oversees the harmonization activities, and contributes to the development of ICH guidelines.

B. Antimicrobial Resistance

In the 2013 Consumer Wash PR and 2015 Health Care Antiseptic PR, FDA raised the concern of the development of antiseptic resistance and its potential impact on the development of antibiotic resistance (78 FR 76444 at 76454 and 80 FR 25166 at 25180). This concern was based on numerous reports of laboratory studies demonstrating the development of reduced susceptibility to certain antiseptic active ingredients and antibiotics after growth in nonlethal amounts of the antiseptic (*i.e.*, low-to-moderate concentrations of antiseptic) and reports of the persistence of low levels of some antiseptic active ingredients in the environment (78 FR 76444 at 76454 and 80 FR 25166 at 25180). FDA concluded in both of these proposed rules that, given the increasing evidence of the magnitude of the antibiotic resistance problem and the speed with which new antibiotic resistant organisms are emerging, it is important to assess this potential consequence of antiseptic use and requested data to address the concern (78 FR 76444 at 76454 and 80 FR 25166 at 25180). However, in its evaluation of the available data on the development of resistance to alcohol and isopropyl alcohol in the proposed rule for health care antiseptics, FDA cited a number of factors (speed of action, multiple nonspecific toxic effects, and lack of a residue) that made the development of resistance to these alcohols as a result of health care antiseptic use unlikely. Based on these factors, FDA concluded that no additional data relevant to this issue were necessary to support a GRAS determination for these ingredients for health care antiseptics (80 FR 25166 at 25184, 25187, and 25192). Consistent with FDA's findings for alcohol and isopropyl alcohol in its proposed rule for health care antiseptic, we have also tentatively concluded that no further data on the development of resistance to alcohol and isopropyl alcohol as a result of their use in consumer antiseptic rub products are needed. This is not the case for benzalkonium chloride for which additional laboratory studies will assist in more clearly defining the potential for the development of resistance. (See section VIII.D.2).

C. Studies To Support a Generally Recognized as Safe Determination

A GRAS determination for consumer antiseptic rub active ingredients must be supported by both nonclinical (animal) and clinical (human) studies.[6] To issue a final monograph for these products, this safety data must be in the docket.[7]

To assist manufacturers or others who wish to provide us with the information we expect will establish GRAS status for these active ingredients, we are including specific information, based in part on existing FDA guidance, about the other kinds of studies to consider conducting and submitting. We have published guidance documents describing the nonclinical safety studies that a manufacturer should perform when seeking to market a drug product under an NDA (Refs. 40, 57 through 63). These guidance documents also provide relevant guidance for performing the nonclinical studies necessary to determine GRAS status for a consumer antiseptic rub active ingredient. Because consumer antiseptic rubs may be used repeatedly and in sensitive populations, we propose that consumer antiseptic rub active ingredients will need to be tested for carcinogenic potential, developmental and reproductive toxicity (DART), and other potential effects as described in more detail in this section.

1. FDA Guidances Describing Safety Studies

The safety studies that are described in the existing FDA guidances (Refs. 40, 57 through 63) provide a framework for the types of studies that are needed for FDA to assess the safety of each consumer rub active ingredient according to modern scientific standards and make a GRAS determination. A description of each type of study and how we would use this information to improve our understanding of the safety of consumer antiseptic rub active ingredients is provided in table 5.

TABLE 5—FDA GUIDANCE DOCUMENTS RELATED TO REQUESTED SAFETY DATA AND RATIONALE FOR STUDIES

Type of study	Study conditions	What the data tell us	How the data are used
Animal pharmacokinetic absorption, distribution, metabolism, and excretion (ADME) (Refs. 58 and 64).	Both oral and dermal administration.	Allows identification of the dose at which the toxic effects of an active ingredient are observed as a result of systemic exposure of the drug. ADME data provide: The rate and extent an active ingredient is absorbed into the body (e.g., AUC, Cmax, Tmax)[1]; where the active ingredient is distributed in the body; whether metabolism of the active ingredient by the body has taken place; information on the presence of metabolites; and how the body eliminates the original active ingredient (parent) and its metabolites (e.g., T½)[2].	Used as a surrogate to identify toxic systemic exposure levels that can then be correlated to potential human exposure via dermal pharmacokinetic study findings. Adverse event data related to particular doses and drug levels (exposure) in animals are used to help formulate a safety picture of the possible risk to humans.

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[6] We encourage sponsors to consult with us on non-animal testing methods they believe may be suitable, adequate, validated, and feasible. We are willing to consider if alternative methods could be assessed for equivalency to an animal test method.

[7] The Agency intends to consider only non-confidential material that is submitted to the docket for this rulemaking or that is otherwise publicly available in its evaluation of the GRAS/GRAE status of a relevant ingredient. Information about how to submit this data or information to the docket is set forth in this document in the **ADDRESSES** section.

TABLE 5—FDA GUIDANCE DOCUMENTS RELATED TO REQUESTED SAFETY DATA AND RATIONALE FOR STUDIES—Continued

Type of study	Study conditions	What the data tell us	How the data are used
Human pharmacokinetics (MUsT) (Ref. 62).	Dermal administration using multiple formulations under maximum use conditions.	Helps determine how much of the active ingredient penetrates the skin, leading to measurable systemic exposure.	Used to relate the potential human exposure to toxic drug levels identified in animal studies.
Carcinogenicity (ICH S1A, S1B, and S1C) (Refs. 40, 57, and 60).	Minimum of one oral and one dermal study for topical products[3].	Provides a direct measure of the potential for active ingredients to cause tumor formation (tumorogenesis) in the exposed animals.	Identifies the systemic and dermal risks associated with drug active ingredients. Taken together, these studies are used to identify the type(s) of toxicity, the level of exposure that produces these toxicities, and the highest level of exposure at which no adverse effects occur, referred to as the "no observed adverse effect level" (NOAEL). The NOAEL is used to determine a safety margin for human exposure.
Developmental toxicity (ICH S5) (Ref. 59).	Oral administration	Evaluates the effects of a drug on the developing offspring throughout gestation and postnatally until sexual maturation.	
Reproductive toxicity (ICH S5) (Ref. 59).	Oral administration	Assesses the effects of a drug on the reproductive competence of sexually mature male and female animals.	
Hormonal effects (Ref. 63).	Oral administration	Assesses the drug's potential to interfere with the endocrine system.	Used in hazard assessment to determine whether the drug has the capacity to induce a harmful effect at any exposure level without regard to actual human exposures.

[1] "AUC" denotes the area under the concentration-time curve, a measure of total exposure or the extent of absorption. "Cmax" denotes the maximum concentration, which is peak exposure. "Tmax" denotes the time to reach the maximum concentration, which aids in determining the rate of exposure.

[2] "T½" denotes the half-life, which is the amount of time it takes to eliminate half the drug from the body or decrease the concentration of the drug in plasma by 50 percent.

[3] Assessment of dermal carcinogenicity is considered important because the intended clinical route of administration of dermal, and skin exposure could be high. In addition, dermal exposure can result in systemic exposure to parent and metabolites that may differ from other routes. When substantial nonclinical information is already available for an active ingredient, the need for a dermal carcinogenicity study could be reconsidered based on available information such as negative systemic carcinogenicity information and lack of preneoplastic effects in chronic nonrodent dermal toxicity studies.

These studies represent FDA's current thinking on the data needed to support a GRAS determination for an OTC antiseptic active ingredient and are similar to those recommended by the Antimicrobial I Panel (described in the ANPR (39 FR 33103 at 33135)) as updated by the recommendations of the 2014 NDAC. However, even before the September 2014 NDAC meeting, the Panel's recommendations for data to support the safety of an OTC topical antimicrobial active ingredient included studies to characterize the following:

- Degree of absorption through intact and abraded skin and mucous membranes.
- Tissue distribution, metabolic rates, metabolic fates, and rates and routes of elimination.
- Teratogenic and reproductive effects.
- Mutagenic and carcinogenic effects.

2. Studies To Characterize Maximal Human Exposure

Because the available data indicate that some dermal products, including at least some antiseptic active ingredients, are absorbed after topical application in humans and animals, it is necessary to assess the effects of long-term dermal and systemic exposure to these ingredients. This is particularly important for populations, such as pregnant women (and fetuses), lactating women, and children, who may have greater potential to experience deleterious developmental effects from drug exposure. Human exposure data can then be compared to drug levels in animals known to produce adverse effects in order to calculate a safety margin.

Based on input from the September 2014 NDAC meeting, the Agency has also determined that results from a human PK maximal usage trial (MUsT) are needed to support a GRAS determination. This trial design is also referred to as a maximal use PK trial and is described in FDA's 2005 draft guidance for industry on developing drugs for treatment of acne vulgaris (Ref. 62). The purpose of the MUsT is to evaluate systemic exposure under conditions that would maximize the potential for drug absorption in a manner consistent with possible "worst-case" real world use of the product. In a MUsT, the collected plasma samples are analyzed, and the resulting in vivo data could be used to estimate a safety margin based on animal toxicity studies.

A MUsT to support a determination that an active ingredient is GRAS for use in consumer antiseptics is conducted by obtaining an adequate number of PK samples following administration of the active ingredient. For studies of active ingredients to be used in topically applied products like these, for which there is less information available and for which crossover designs are not feasible, a larger number of subjects are required compared to studies of orally administered drug products. A MUsT using 50 to 75 subjects per cohort should be sufficient to get estimates of the PK parameters from a topically applied consumer antiseptic.

The MUsT should attempt to maximize the potential for drug absorption to occur by considering the following design elements (Ref. 65):

- Adequate number of subjects (steps should be taken to ensure that the target population (for example, age, gender, race) is properly represented).
- Frequency of dosing (*e.g.,* number of rub applications during the study).
- Duration of dosing.

- Use of highest proposed strength (*e.g.,* 95 percent alcohol).
- Total involved surface area to be treated at one time (*e.g.,* hands).
- Amount applied per square centimeter.
- Method of application (*e.g.,* rub).
- Sensitive and validated analytical methods.

It also is important that the MUsT reflect maximal use conditions of consumer antiseptic rubs using different formulations to fully characterize the active ingredient's potential for dermal penetration. There are very limited data on the maximal number of uses of antiseptic rubs in consumer settings. Consumer antiseptic rubs used in institutional settings, such as daycare centers, schools, and office buildings, would be used (as per label directions) at higher rates than in domestic households, and thus would represent maximal use. Kinnula et al. (2009) surveyed workers in child daycare centers in Finland to determine how commonly alcohol-containing hand rub gels were applied daily (Ref. 66). The respondents (n = 128) reported applying the alcohol hand rub gels up to 50 times per day. Using the upper limit of applications per day of antiseptic hand rubs from this study, FDA is considering 50 times per day as the maximal use of consumer hand rubs in a consumer setting.

It should be noted that a systemic carcinogenicity study will not be required for an ingredient if a MUsT results in a steady state blood level less than 0.5 nanograms (ng)/mL, and an adequately conducted toxicology program demonstrates that there are no other signals for the ingredient or any known structurally similar compound indicating the potential for adverse effects at lower levels. The threshold value of 0.5 ng/mL is based on the principle that the level would approximate the highest plasma level below which the carcinogenic risk of any unknown compound would be less than 1 in 100,000 after a single dose.

The lack of absorption in a MuST does not alleviate the need to assess dermal carcinogenicity because the magnitude of exposure to the skin can be much higher than would be covered by systemic studies. In addition, systemic exposure to the parent compound and metabolites can differ significantly for a dermally applied product because the skin has metabolic capability and first-pass metabolism is bypassed via this route of administration.

To fulfill the maximum human exposure requirement, the MUsT study should meet appropriate design standards using the highest concentration sought under this proposed rule in formulations expected to produce the highest in vivo absorption. The assay used in the MUsT should be properly validated according to current Good Laboratory Practices and consistent with FDA guidance for industry: "Bioanalytical Method Validation" (Ref. 67).

We expect that the 0.5 ng/mL concentration will be sufficiently above the assay's limit of quantitation-limit of detection to allow a signal: Noise ratio that assures confidence in the derived concentrations (in the case of "exaggerated" values) or lack of concentrations.

3. Studies To Characterize Hormonal Effects

We propose that data are also needed to assess whether consumer antiseptic rub active ingredients have hormonal effects that could produce developmental or reproductive toxicity. There are several factors common to antiseptic products that make it necessary to assess their full safety profile prior to classifying an antiseptic active ingredient as GRAS for use in consumer antiseptic rub products. These factors are as follows:

- Evidence of systemic exposure to several of the antiseptic active ingredients.
- Exposure to multiple sources of antiseptic active ingredients that may be hormonally active compounds.
- Exposure to antiseptic active ingredients may be long term for some users.

According to FDA's 2015 guidance on nonclinical evaluation of endocrine-related drug toxicity (Ref. 63), endocrine effects may be identified from the standard battery of toxicity tests conducted during drug development and may not require additional separate studies.

4. Studies To Evaluate the Potential Impact of Antiseptic Active Ingredients on the Development of Resistance

Since the 1994 TFM published, the issue of antiseptic resistance and whether bacteria that exhibit antiseptic resistance have the potential for antibiotic cross-resistance has been the subject of much study and scrutiny. One of the major mechanisms of antiseptic and antibiotic cross-resistance is changes in bacterial efflux activity at nonlethal concentrations of the antiseptic (Refs. 68 through 73). Efflux pumps are an important nonspecific bacterial defense mechanism that can confer resistance to a number of substances toxic to the cell, including antibiotics (Refs. 74 and 75). The development of bacteria that are resistant to antibiotics is an important public health issue, and additional data may tell us whether use of antiseptics in consumer settings may contribute to the selection of bacteria that are less susceptible to both antiseptics and antibiotics. Therefore, we are requesting additional data and information to address this issue for ingredients other than alcohol or isopropyl alcohol (see section VIII.D).

FDA believes that a tiered approach is an efficient means of developing data to address this issue. Laboratory studies in conjunction with a literature review are a feasible first step in evaluating the impact of exposure to nonlethal amounts of antiseptic active ingredients on antiseptic and antibiotic bacterial susceptibilities. However, only limited data exist on the effects of antiseptic exposure on the bacteria that are predominant in the oral cavity, gut, skin flora, and the environment (Ref. 76). These organisms represent pools of resistance determinants that are potentially transferable to human pathogens (Refs. 77 and 78). Thus, broader laboratory testing of consumer antiseptic active ingredients would more clearly define the scope of the impact of antiseptic active ingredients on the development of antibiotic resistance and may be able to identify those antiseptic active ingredients for which the development of resistance is not a concern. Laboratory studies evaluating the antiseptic and antibiotic susceptibilities of bacteria grown in the presence of sublethal concentrations of antiseptic active ingredients could help support a GRAS determination for antiseptic active ingredients intended for use in OTC consumer antiseptic drug products. The following types of organisms should be evaluated:

- Human bacterial pathogens.
- Nonpathogenic organisms, opportunistic pathogens, and obligate anaerobic bacteria that make up the resident microflora of the human skin, gut, and oral cavity.
- Food-related bacteria such as *Listeria, Lactobacillus,* and *Enterococcus.*
- Nonpathogenic organisms and opportunistic pathogens from relevant environmental sources (*e.g.,* soil).

If the results of these studies show no evidence of changes in antiseptic or antibiotic susceptibility, no further studies addressing the development of resistance would be needed to support a GRAS determination.

For antiseptic active ingredients that demonstrate an effect on antiseptic and antibiotic susceptibilities, additional data will be necessary to help assess the likelihood that similar effects would occur in the consumer setting. Several types of data could be used to assess whether or not ingredients with positive laboratory findings pose a public health risk, and the type of data needed would depend on what is already known about the antiseptic active ingredient's mechanism of action and persistence in the environment. We do not anticipate that it will be necessary to obtain data from multiple types of studies for each active ingredient to adequately assess its potential to affect resistance. Such types of data could include, but are not limited to, the following:

- Information about the mechanism(s) of antiseptic action (for example, membrane destabilization or inhibition of fatty acid synthesis), and whether there is a change in the mechanism of action with changes in antiseptic concentration.
- Information clarifying the bacteria's mechanism(s) for the development of resistance or reduced susceptibility to the antiseptic active ingredient (for example, efflux mechanisms).
- Data characterizing the potential for reduced antiseptic susceptibility caused by the antiseptic active ingredient to be transferred to other bacteria that are still sensitive to the antiseptic.
- Data characterizing the concentrations and antimicrobial activity of the antiseptic active ingredient in biological and environmental compartments (for example, bacteria found on human skin, in the gut, and in environmental matrices).
- Data characterizing the antiseptic and antibiotic susceptibility levels of environmental isolates of bacteria in areas of prevalent antiseptic use, such as in the home or in schools.

Data from the types of testing described previously, as well as from testing of antiseptic and antibiotic susceptibilities of bacteria in settings where consumer topical antiseptic rub use is prevalent can help demonstrate whether or not changes in susceptibility are occurring with actual use. Because actual use concentrations of consumer antiseptics are much higher than the MICs for these active ingredients, data from compartments where sublethal concentrations of biologically active antiseptic active ingredients may occur (*e.g.*, environmental compartments) can give us a sense of the potential for change in antimicrobial susceptibilities in these compartments (Refs. 79 through 81). FDA recognizes, however, that methods of evaluating this issue are an evolving science and that there may be other data appropriate to evaluate the impact of consumer antiseptic active ingredients on the development of resistance. For this reason, FDA encourages interested parties to consult with the Agency on the specific studies appropriate to address this issue for a particular active ingredient.

D. Review of Available Data for Each Antiseptic Active Ingredient

We have identified for each consumer antiseptic rub active ingredient whether the studies outlined in section VIII.C are publicly available. Table 6 lists the types of studies available for each antiseptic active ingredient eligible for use as a consumer rub proposed as Category I or Category III in the 1994 TFM and indicates whether the currently available data are adequate to serve as the basis of a GRAS determination. Although we have some data from submissions to the rulemaking and from information we have identified in the literature, our administrative record is incomplete for at least some types of safety studies for each of the active ingredients (see table 6). As noted previously, only information that is part of the administrative record for this rulemaking can form the basis of a GRAS/GRAE determination.

We recognize that data and information submitted in response to the 2013 Consumer Wash PR or 2015 Health Care Antiseptic PR may be relevant to this proposed rule. At the time of publication of this proposed rule, FDA's review of all submissions made to the 2015 Health Care Antiseptic PR has not been completed. FDA requests that any information relevant to consumer antiseptic rub active ingredients be resubmitted under this docket (FDA–2016–N–0124).

TABLE 6—SAFETY STUDIES AVAILABLE FOR CONSUMER ANTISEPTIC HAND RUB ACTIVE INGREDIENTS[1]

Active Ingredient	Human Pharmaco-kinetic (MUsT)	Animal Pharmaco-kinetic (ADME)	Oral Carcino-genicity	Dermal Carcino-genicity	Reproductive Toxicity (DART)	Potential Hormonal Effects	Resistance Potential
Alcohol	○	•	•	•	•	•	•
Benzalkonium chloride		○	•		•	•	○
Isopropyl alcohol	○	○		○	•	○	•

[1] Empty cell indicates no data available; "○" indicates incomplete data available; "•" indicates available data are sufficient to make a GRAS/GRAE determination.

In the remainder of this section, we discuss the existing data and data gaps for alcohol, benzalkonium chloride and isopropyl alcohol, the consumer antiseptic rub active ingredients that were proposed as GRAS in the 1994 TFM, and explain why these active ingredients are no longer proposed as GRAS for use in consumer antiseptic hand rubs (*i.e.*, why they are now proposed as Category III). We also discuss benzalkonium chloride, which was proposed as Category III in the 1994 TFM and for which there are some new data available and explain why this ingredient is still Category III. These three ingredients are also used in health care antiseptic products, and the safety data gaps identified in the 2015 Health Care Antiseptic PR are similar to those discussed in this proposed rule for each ingredient. The requirements for a GRAS determination for an ingredient are generally the same for either a health care or consumer antiseptic product, with the exception of higher maximal use for health care antiseptic products. Therefore, it is anticipated that ingredients fulfilling the requirements for a health care antiseptic GRAS determination would also meet the criteria for GRAS as a consumer antiseptic, if eligible for that indication.

1. Alcohol

In the 1994 TFM, FDA proposed to classify alcohol as GRAS for all health care antiseptic uses based on the recommendation of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel), which concluded that the topical application of alcohol is safe (59 FR 31402 at 31412). In the 2013 Consumer Wash PR, FDA proposed to separately evaluate the safety and effectiveness of the OTC antiseptic drug products by use setting, specifically health care and consumer antiseptic products. As defined in the 2013 Consumer Wash PR, consumer antiseptic products that are not rinsed off after use include hand rubs and antiseptic wipes. FDA is proposing to classify alcohol as Category III for use in consumer antiseptic rubs. Extensive studies have been conducted to characterize the metabolic and toxic effects of alcohol in animal models. Although the impetus for most of the studies has been to study the effects of alcohol exposure via the oral route of administration, some dermal toxicity studies are available and have shown that, although there is alcohol absorption through human skin, it is much lower than absorption via the oral route. Overall, there are adequate safety data to make a GRAS determination for alcohol, with the exception of human pharmacokinetic data under maximal use conditions.

a. *Summary of alcohol safety data.* As discussed in more detail in the 2015 Health Care Antiseptic PR (80 FR 25166 at 25185 to 25187), FDA has reviewed the following and found them to be sufficient to characterize the safety of alcohol for use in consumer antiseptic rubs:

- Animal ADME data demonstrating absorption of alcohol both in vitro and in vivo (Refs. 82 through 86).
- Dermal and oral carcinogenicity data in animals and oral carcinogenicity data in humans (Refs. 87 through 93).
- DART human data (Refs. 94 and 95).
- Data on the hormonal effects of alcohol in animals and humans (Refs. 96 through 102).
- Data on the antimicrobial mechanism of alcohol (Refs. 103 through 106). Alcohol readily evaporates from the skin after topical application, and the resulting lack of antiseptic residue on the skin suggests that the topical application of alcohol is not likely to contribute to the development of antimicrobial resistance (Refs. 103, 105).

Alcohol human pharmacokinetic data. The 2015 Health Care Antiseptic PR described data that characterize the level of dermal absorption and expected systemic exposure in adults as a result of topical use of alcohol-containing antiseptics (80 FR 25166 at 25185–25186). These data do not cover maximal use of these products as detailed in section VIII.D.1.a.

A variety of alcohol-based hand rub product formulations and alcohol concentrations have been used in these studies. Based on the available data, which represents moderate hand rub use (7.5 to 40 hand rub applications per hour, studied for 30 to 240 minutes), the highest observed exposure was 1,500 milligrams (mg) of alcohol (Ref. 4), which is the equivalent of 10 percent of an alcohol-containing drink. See also the discussion of occupational exposure to alcohol via the dermal route (Ref. 107) in the alcohol carcinogenicity section of the 2015 Health Care Antiseptic PR (80 FR 25166 at 25186).

Although these data do indicate absorption of alcohol does occur after topical administration of alcohol-containing antiseptic rubs, we did not find the exposure conditions of these studies comparable to exposure that are required by our current MUsT standards specified in section VIII.C.2. Consequently, human pharmacokinetic data under maximal use conditions as determined by a MUsT are needed to make a GRAS determination for the alcohol-containing consumer antiseptic rubs.

b. *Alcohol safety data gap.* In summary, our administrative record for the safety of alcohol is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure alcohol and its metabolites.

2. Benzalkonium Chloride

In the 1994 TFM, FDA categorized benzalkonium chloride as Category III because of a lack of adequate safety data for its use as both a health care antiseptic and consumer antiseptic product (59 FR 31402 at 31435). FDA also is proposing to classify benzalkonium chloride as Category III for the indication of consumer antiseptic rubs. Thus, additional safety data are still needed to make a GRAS determination for benzalkonium chloride for use as a consumer antiseptic rub.

In the 2013 Consumer Wash PR, FDA identified the safety data needed to make a GRAS determination for benzalkonium chloride as an ingredient in consumer antiseptic wash products. The safety gaps listed were human and animal pharmacokinetic data, reproductive toxicity studies, potential hormonal effects, carcinogenicity (oral and dermal) studies, and potential of the development of antimicrobial resistance to benzalkonium chloride. As was summarized in the 2015 Health Care Antiseptic PR, the safety of benzalkonium chloride has been reviewed and was determined to be safe for use in disinfectants and cosmetic products by the Environmental Protection Agency (EPA) and the Cosmetic Ingredient Review (an industry panel), respectively (Refs. 108 and 109). The data cited in both of these evaluations are proprietary and only summaries of the data are publicly available. Consequently, these studies are not available to FDA and FDA cannot conduct a complete evaluation of them. Safety assessments with study summaries do not constitute an adequate record on which to base a GRAS classification (§ 330.10(a)(4)(i)). For FDA to evaluate this data with respect to the safety of benzalkonium chloride for this rulemaking, the full study reports and data sets must be submitted to the rulemaking docket or otherwise be publicly available.

In response to the call for data in the 2013 Consumer Wash PR, a manufacturing consortium submitted the following studies to the 2013 Consumer Wash PR docket (Refs. 110 through 121):

- An embryofetal toxicity study in the rabbit;
- an embryofetal toxicity study in the rat;
- a 2-generation study in the rat;
- a 90 day subchronic dietary study in rats;
- a 90 day subchronic dermal toxicity study in rats;
- a 1-year chronic dietary toxicity study in dogs;
- an ADME study in rats;
- a rat oral carcinogenicity study; and
- a mouse oral carcinogenicity study.

All of these studies have been reviewed by FDA. Some of the data were found to be adequate to fill some of the safety data gaps for a GRAS determination for benzalkonium chloride. Data gaps remain for the following endpoints: Human pharmacokinetic data under maximal use condition, animal dermal carcinogenicity and animal ADME data, and data on antimicrobial resistance to benzalkonium chloride.

a. *Summary of benzalkonium chloride safety data.*

Benzalkonium chloride ADME data. ADME studies of ADBAC in rats of both sexes were conducted using the oral and the intravenous (IV) routes of administration. In the oral studies, rats were administered radiolabeled benzalkonium chloride using the following cohorts: A low-dose single oral administration study (10 mg/kilogram (kg)), a low-dose repeated oral administration study (10 mg/kg) and a high-dose single oral administration study (50 mg/kg) (Ref. 115). For the low-dose repeated oral administration study, rats were treated via freely available feed containing 100 parts per million (ppm) of non-radiolabeled benzalkonium chloride for 14 days, followed by administration of 10 mg/kg benzalkonium chloride by oral gavage. Benzalkonium chloride was found to be excreted mainly via the feces in rats after oral administration. In all of the treated groups, the average amount of radioactivity recovered was 87 to 99 percent in the feces and 5 to 8 percent in the urine.

In a separate group of animals tested in the same study, a single low-dose of 10 mg/kg benzalkonium chloride was administered to rats of both sexes. The average amount of radioactivity recovered following IV dosing was 45 to 55 percent in the feces and 20 to 30 percent in the urine. Tissue residues of radioactivity were less than 1 percent of the orally administered dose in all groups and 30 to 35 percent of the IV dose. No significant changes were noted when comparing the ADME profile of high dose versus low dose-treated rats. Although the available ADME data from nondermal routes of exposure are sufficient to characterize the ADME profile of benzalkonium chloride following nondermal exposure, they are not sufficient to characterize the ADME profile after dermal exposure. Studies on animal ADME after dermal exposure to benzalkonium chloride will need to be submitted to FDA for review, in order to complete a GRAS determination for benzalkonium chloride.

Benzalkonium general toxicity data. Two subchronic 90-day toxicity studies in rats were submitted, one dermal and the other dietary (oral). A 1-year chronic oral toxicity study in dogs was also submitted. In the oral rat study, benzalkonium chloride was administered via feeding with concentrations ranging from 0 to 8,000 ppm (Ref. 111) for 13 weeks. Among rats treated with 4,000 and 8,000 ppm benzalkonium chloride, an increased incidence in mortality and overt toxicity was seen. A no adverse effect level (NOAEL) of 500 ppm was noted, which correlated with a mean daily dose of 31.2 mg/kg in males and 38.3 mg/kg in females.

A 1-year chronic oral toxicity study in dogs was also submitted. Dogs were chronically administered benzalkonium chloride via feeding in concentrations ranging from 0 to 1,200 ppm for 1 year (Ref. 114). Changes in body weight included reduced absolute body weight and reduced body weight gain in males and females in the highest group tested (1,200 ppm), which correlated with a reduction in food consumption. At 1,200 ppm, cholesterol levels were reduced by about 10 percent in both males and females ($p \leq 0.01$). No specific organ toxicity was identified. Based on the changes in body weight and food consumption at 1,200 ppm, a NOAEL of 400 ppm was determined, which corresponds to 13.1 and 14.6 mg/kg/day in males and females, respectively.

In the dermal toxicity study, rats were topically exposed to benzalkonium chloride in concentrations ranging from 0 (water) to 1.0 percent (which correspond to 0 to 20 mg/kg/day) over a 13-week treatment period (Ref. 113). Slight local irritation and hyperkeratosis (thickening of the epidermis) were observed in all treatment groups (including control) in both sexes. All findings were limited to the treatment site. Under the conditions of this study, the NOAEL was 20 mg/kg (1.0 percent). Toxicokinetic data were not collected; therefore, systemic exposure to benzalkonium chloride was not characterized. Consequently, dermal ADME (toxicokinetic) data is still needed to characterize benzalkonium chloride.

Benzalkonium chloride carcinogenicity data. Two oral carcinogenicity studies, one in the rat and another in the mouse, were submitted (Refs. 117 through 121). Both studies were conducted in the 1980's prior to the current ICH guidelines. They were conducted according to the OECD (Organisation for Economic Co-operation and Development) guidelines[8] and designed to meet the requirements of EPA's regulations, which use a different type of exposure risk assessment analysis than is used by FDA for drug products.

A 78-week dietary carcinogenicity study was conducted in mice with benzalkonium chloride concentrations of 500, 1,000, and 1,500 ppm, corresponding to approximately 15, 73, and 229 mg/kg/day in males and 18, 92, 289 mg/kg/day in females (Refs. 120 and 121). Findings were limited to decreased body weight in both males and females treated with the highest dose compared to controls (7 percent and 5 percent at week 78 in males and females, respectively). There were no treatment-related increases in the incidence of neoplasms at any of the doses tested.

A 2-year oral carcinogenicity study was conducted in rats with benzalkonium chloride concentrations of 300, 1,000, and 2,000 ppm, corresponding to 13, 44, and 88 mg/kg/day, respectively, in males, and to 17, 57, and 116 mg/kg/day, respectively, in females (Refs. 117 through 119). No treatment-related increases in the incidence of neoplasms were observed at any of the tested doses.

There were no treatment-related neoplasms in either oral carcinogenicity study. Though the mouse study is suboptimal because of its relatively short duration (78 weeks), we believe these two studies are adequate to fill the oral carcinogenicity data gap for benzalkonium chloride.

No dermal carcinogenicity studies of benzalkonium chloride have been submitted to FDA. The available data are not adequate to assess the carcinogenic potential of benzalkonium chloride. We propose that dermal carcinogenicity studies are still needed to complete a GRAS determination for benzalkonium chloride.

Benzalkonium chloride DART data. A developmental toxicity study conducted in rabbits showed some increase (not dose-related) in the incidence of certain visceral and skeletal malformations among benzalkonium chloride-treated rabbits relative to concurrent controls (Ref. 110). None of the findings were considered significant. Some of the mated dams proved to be not pregnant; therefore, the total number of litters (13 to 15) is slightly less than the 16 to 20 recommended in the ICH S5 guideline, but further benzalkonium chloride DART data are not necessary to make a GRAS determination.

In a developmental toxicity study in rats, the animals were administered benzalkonium chloride (10, 30, and 100 mg/kg/day) (Ref. 112). There were no treatment-related differences in gestational parameters, including total number of embryonic implantations, number of viable and nonviable implants. There were also no treatment-related effects on fetal body weights per litter, or on the incidences of external, visceral, or skeletal malformations/variations. Based on these findings, a NOAEL for maternal toxicity was considered to be 10 mg/kg/day and for developmental toxicity 100 mg/kg/day.

A two-generation reproduction and development study in rats was submitted for review. Rats were exposed to benzalkonium chloride in the feed (Ref. 116). The exposure to benzalkonium chloride up to the highest dose tested of 2,000 mg/kg did not result in parental toxicity. No treatment-related reproductive effects were observed in any of the treatment groups. Findings were limited to decreases in body weight accompanied by a decrease in food consumption among treated females at 2,000 mg/kg/day and a decrease in pup body weight. Based on these findings, a NOAEL for adults and offspring was considered to be 1000 ppm (62.5 mg/kg/day).

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[8] *http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788.*

The submitted DART studies are adequate and no additional DART studies are needed for benzalkonium chloride.

Hormonal effects. Based on the negative findings in the carcinogenicity studies and the two-generation DART studies, no signal for hormonal effects was detected and no further testing on hormonal effects will be required for benzalkonium chloride.

Antimicrobial resistance. In addition to the summaries, as discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76463), FDA has reviewed studies on resistance data and antibiotic susceptibility of certain bacteria related to the development of resistance to benzalkonium chloride (Refs. 122 through 129), and determined that the available studies have examined few bacterial species, provide no information on exposure levels, and are not adequate to define the potential for the development of resistance or cross resistance. Additional data are needed to more clearly define the potential for the development of resistance to benzalkonium chloride.

b. Benzalkonium chloride safety data gaps.

In summary, our administrative record for the safety of benzalkonium chloride is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure benzalkonium chloride and its metabolites;
- Animal dermal ADME;
- Dermal carcinogenicity; and
- Data from laboratory studies that assess the potential for the development of resistance to benzalkonium chloride and cross-resistance to antibiotics as discussed in section VIII.C.

3. Isopropyl Alcohol

In the 1994 TFM, FDA proposed to classify isopropyl alcohol (70 to 91.3 percent) as GRAS for all consumer antiseptic washes (59 FR 31402 at 31435). FDA is now proposing to classify isopropyl alcohol as Category III for use in consumer antiseptic rubs. The GRAS determination in the 1994 TFM was based on the recommendations of the Miscellaneous External Panel, which based its recommendations on human absorption data and blood isopropyl alcohol levels (47 FR 22324 at 22329). There was no comprehensive nonclinical review of the toxicity profile of isopropyl alcohol, nor was there a nonclinical safety evaluation of the topical use of isopropyl alcohol.

a. *Summary of isopropyl alcohol safety data.*

As discussed in more detail in the 2015 Health Care Antiseptic PR (80 FR 25166 at 25190–25193), FDA has reviewed the following data and found the data to be sufficient to characterize the safety of isopropyl alcohol:

- DART data (Refs. 130 through 135).
- Data on the antimicrobial mechanism of isopropyl alcohol (Refs. 103 through 106, 136 through 138). Isopropyl alcohol readily evaporates from the skin after topical application. The lack of antiseptic residue on the skin indicates that the topical application of isopropyl alcohol is not likely to contribute to the development of antimicrobial resistance (Refs. 103, 105). Additional data on the development of antimicrobial resistance are not needed to make a GRAS determination.

No new data has been made available to FDA since publication of the 1994 TFM that can fill any of the remaining safety data gaps for isopropyl alcohol. The following areas of safety assessment, which were identified in the 1994 TFM and discussed in detail in the 2015 Health Care Antiseptic PR (80 FR 25166 at 25190–25193), are being updated in this document:

- Human absorption data (Refs. 1, 139 through 142). However, the data submitted and found in the literature to date do not cover maximal use of these products in an institutional setting as detailed in section VIII.C.2.
- Animal ADME data following dermal and systemic exposure to isopropyl alcohol (Refs. 143 through 149). The available dermal exposure studies have demonstrated that there is some systemic exposure to isopropyl alcohol following dermal application. However, the extent of that exposure has not been fully characterized. Moreover, absorption data following dermal absorption in animals are still needed to determine the extent of systemic exposure following maximal dermal exposure to isopropyl alcohol-containing consumer antiseptic rub products.
- Systemic and dermal carcinogenicity data in animal models. Available data for chronic exposure to isopropyl alcohol include inhalation carcinogenicity data in rodents (Refs. 150 and 151) and a chronic 1-year dermal toxicity study in mice (Ref. 149). However, these data are not adequate to assess the systemic or dermal carcinogenic potential of isopropyl alcohol.
- Data on the hormonal effects of isopropyl alcohol. The existing data are not adequate to characterize the potential for hormonal effects of isopropyl alcohol. However, additional studies may not be needed to assess the potential hormonal effects of isopropyl alcohol if assessment of potential hormonal activity can be derived from existing (reproductive and developmental studies; chronic general toxicity data) and additional pending isopropyl alcohol (systemic and dermal carcinogenicity and ADME data) nonclinical studies, provided the appropriate endpoints are assessed.

Thus, we believe the existing evaluations need to be supplemented to fully evaluate the safety of isopropyl alcohol. As described in more detail in the 2015 Health Care Antiseptic PR (80 FR 25166 at 25190–25193), we propose that human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), animal ADME studies (dermal absorption), systemic and dermal carcinogenicity studies, and data on hormonal effects are still needed to complete a GRAS determination for isopropyl alcohol.

b. Isopropyl alcohol safety data gaps.

In summary, our administrative record for the safety of isopropyl alcohol is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure isopropyl alcohol and its metabolites;
- animal ADME (dermal absorption);
- dermal carcinogenicity;
- systemic carcinogenicity (may be waived if the MUsT data do not show absorption); and
- hormonal effects (could be derived from other endpoints).

IX. Proposed Effective Date

Based on the currently available data, this proposed rule finds that additional data are necessary to establish the safety and effectiveness of consumer antiseptic rub active ingredients for use in OTC consumer antiseptic rub drug products. Accordingly, consumer antiseptic rub active ingredients would be nonmonograph in any final rule based on this proposed rule. We recognize, based on the scope of products subject to this monograph, that manufacturers will need time to comply with a final rule based on this proposed rule. However, because of the potential effectiveness and safety considerations raised by the data for some antiseptic active ingredients evaluated, we believe that an effective date later than 1 year after publication of the final rule would not be appropriate or necessary. Consequently, any final rule that results from this proposed rule will be effective 1 year after the date of the final rule's publication in the **Federal Register**. On or after that date, any OTC consumer antiseptic rub drug product that is subject to the monograph and that contains a nonmonograph condition, *i.e.*, a condition that would cause the drug to be not GRAS/GRAE or to be misbranded, could not be introduced or delivered for introduction into interstate commerce unless it is the subject of an approved new drug application or abbreviated new drug application. Any OTC consumer antiseptic rub drug product subject to the final rule that is repackaged or relabeled after the effective date of the final rule would be required to be in compliance with the final rule, regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

X. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the consumer antiseptic rub product industry is mainly composed of establishments with 500 or fewer employees, we tentatively conclude that the proposed rule may have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

There are three active ingredients being evaluated for use as a consumer antiseptic rub in this proposed rule: Alcohol (ethanol or ethyl alcohol), isopropyl alcohol, and benzalkonium chloride. The impact of the proposed rule on OTC consumer antiseptic rub product industry will depend on the outcome of tests to determine whether these three active antiseptic ingredients are GRAS/GRAE. It is possible that none, one, two, or all three of the ingredients will be determined to be GRAS/GRAE. We consider two extreme scenarios to capture the entire range of total costs: (1) All three ingredients are deemed to be GRAS/GRAE or (2) none of the ingredients is deemed to be GRAS/GRAE.

In table 7, we provide a summary of the estimated costs of the proposed rule for the two scenarios. The costs of the proposed rule involve product reformulation and relabeling of products. It is important to note that, to demonstrate that an antiseptic active ingredient is GRAS/E, some manufacturers will also incur additional costs associated with safety and effectiveness testing. We note that the testing costs for this proposed rule are not attributed here because these costs will be realized if manufacturers conduct the testing discussed in the proposed rule for health care antiseptics (80 FR 25166) and we do not count costs twice. However, we estimate these costs in this analysis to promote transparency in the event that this rule is finalized before the health care antiseptics proposed rule or manufacturers conduct the testing for the three ingredients discussed in this rule but do not conduct the testing for these ingredients for the health care antiseptic proposed rule ~~or this rule is finalized but the health care antiseptics proposed rule is not.~~

In scenario 1, all three ingredients are determined to be GRAS/E and manufacturers of products containing other ingredients will no longer be able to market these products under consumer antiseptic rub labels pursuant to the topical antimicrobial monograph. We expect that these manufacturers will reformulate their products to contain one of the monograph ingredients and relabel their products to reflect the change in ingredients. Annualizing upfront costs over a 10-year period at a discount rate of 3% for scenario 1, the costs of the proposed rule are estimated to be between $0.04 million and $0.12 million per year; the corresponding estimated cost at a discount rate of 7% is between $0.05 million and $0.14 million per year. In scenario 2, none of the ingredients is determined to be GRAS/E and we expect that manufacturers will reformulate their products to be free of antiseptics and relabel them to reflect the change in ingredients. Annualizing upfront costs over a 10-year period at a discount rate of 3% for scenario 2, the costs of the proposed rule are estimated to be between $1.87 million and $5.52 million per year; the corresponding estimated cost at a discount rate of 7% is between $2.28 million and $6.70 million per year.

TABLE 7—SUMMARY OF QUANTIFIED TOTAL COSTS (IN MILLIONS), BY SCENARIO

Cost category	One-time costs			Annualized costs over a 10-year period					
	Low	Med.	High	3% Discount rate			7% Discount rate		
				Low	Med.	High	Low	Med.	High
Scenario 1: Assuming All Ingredients are Determined to be GRAS/E									
Relabeling Costs	$0.11	$0.19	$0.32	$0.01	$0.02	$0.04	$0.02	$0.03	$0.05
Reformulation Costs	0.23	0.46	0.70	0.03	0.05	0.08	0.03	0.07	0.10
Total Costs	0.34	0.66	1.02	0.04	0.08	0.12	0.05	0.09	0.14

TABLE 7—SUMMARY OF QUANTIFIED TOTAL COSTS (IN MILLIONS), BY SCENARIO—Continued

Cost category	One-time costs			Annualized costs over a 10-year period					
				3% Discount rate			7% Discount rate		
	Low	Med.	High	Low	Med.	High	Low	Med.	High
Scenario 2: Assuming None of the Ingredients is Determined to be GRAS/E									
Relabeling Costs	6.55	11.36	18.76	0.77	1.33	2.20	0.93	1.62	2.67
Reformulation Costs	9.44	18.89	28.33	1.11	2.21	3.32	1.34	2.69	4.03
Total Costs	15.99	30.25	47.09	1.87	3.55	5.52	2.28	4.31	6.70

A potential benefit of the proposed rule is that the removal of potentially harmful antiseptic active ingredients in consumer antiseptic rub products will prevent health consequences associated with exposure to such ingredients. FDA lacks the necessary information to estimate the impact of exposure to antiseptic active ingredients in consumer antiseptic rub products on human health outcomes. We are, however, able to estimate the reduction in the aggregate exposure to antiseptic active ingredients found in currently marketed consumer antiseptic rub products. As with the total costs, the reduction in aggregate exposure to antiseptic active ingredients in consumer rub products depends on the outcome of testing and the determination of GRAS/E status of the three ingredients that require testing. The proposed rule will lead to an estimated reduction that ranges from 110 pounds to 254 pounds per year in scenario 1 and from 13,080,963 and 67,272,847 pounds per year in scenario 2. Absent information on the change in the short- and long-term health risks associated with a one pound increase in exposure to each antiseptic active ingredient in consumer antiseptic rub products, we are unable to translate the aggregate exposure figures into monetized benefits.

FDA also examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This proposed rule could impose a significant economic impact on a substantial number of small entities. For small entities, we estimate the rule's one-time costs to roughly range between 0.001 and 0.16 percent of average annual value of shipments for a small business. In the Initial Regulatory Flexibility Analysis, we assess regulatory options that would reduce the proposed rule's burden on small entities, such as extending relabeling compliance times to 18 months (rather than 12 months).

The full analysis of economic impacts is available in the docket for this proposed rule (Docket No. FDA–2016–N–0124) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

XI. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." The sole statutory provision giving preemptive effect to this proposed rule is section 751 of the FD&C Act (21 U.S.C. 379r). We have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effect of this proposed rule, if finalized, would be consistent with Executive Order 13132. Through publication of this proposed rule, we are providing notice and an opportunity for State and local officials to comment on this rulemaking.

XIV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Brown, T.L. et al., "Can Alcohol-Based Hand-Rub Solutions Cause You to Lose Your Driver's License? Comparative Cutaneous Absorption of Various Alcohols," *Antimicrobial Agents and Chemotherapy,* 51:1107–1108, 2007. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1803104/.*
2. Calafat, A.M. et al., "Urinary Concentrations of Triclosan in the U.S. Population: 2003–2004," *Environmental Health Perspective,* 116:303–307, 2008. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2265044/.*
3. Centers for Disease Control and Prevention, "Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, July 2010," 2010. Available at *http://www.cdc.gov/exposurereport/.*
4. Kramer, A. et al., "Quantity of Ethanol Absorption After Excessive Hand Disinfection Using Three Commercially Available Hand Rubs Is Minimal and Below Toxic Levels for Humans," *BioMed Central Infectious Diseases,* 7:117, 2007. Available at *http://www.pubfacts.com/detail/17927841/Quantity-of-ethanol-absorption-after-excessive-hand-disinfection-using-three-commercially-available-.*
5. Miller, M.A. et al., "Does the Clinical Use of Ethanol-Based Hand Sanitizer Elevate Blood Alcohol Levels? A Prospective Study," *American Journal of Emergency Medicine,* 24:815–817, 2006. Available at *http://www.ajemjournal.com/article/S0735-6757(06)00131-8/pdf.*
6. Transcript of the January 22, 1997, Meeting of the Joint Nonprescription Drugs and

Anti-Infective Drugs Advisory Committees, OTC Vol. 230002. Available in Docket No. FDA 2015–N–0101 at *http://www.regulations.gov.*

7. Comment submitted in Docket No. FDA–1975–N–0012 available at *http://www.regulations.gov* with Comment No. FDA–1975–N–0012–0081.
8. Transcript of the March 23, 2005, Nonprescription Drugs Advisory Committee. Available in Docket No. FDA 2015–N–0101 at *http://www.regulations.gov.*
9. Transcript of the October 20, 2005, Meeting of the Nonprescription Drugs Advisory Committee, available at *http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4184T1.pdf.*
10. Summary Minutes of the November 14, 2008, Feedback Meeting with Personal Care Products Council and Soap and Detergent Association, OTC Vol. 230002. Available in Docket No. FDA 2015–N–0101 at *http://www.regulations.gov.*
11. Transcript of the September 3, 2014, Meeting of the Nonprescription Drugs Advisory Committee, available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM421121.pdf,* 2014.
12. Comments submitted in Docket No. FDA–1975–N–0012 available at *http://www.regulations.gov* with Comment Nos. FDA–1975–N–0012–0037, FDA–1975–N–0012–0049, FDA–1975–N–0012–0068, FDA–1975–N–0012–0071, FDA–1975–N–0012–0073, FDA–1975–N–0012–0075, FDA–1975–N–0012–0081, FDA–1975–N–0012–0082, FDA–1975–N–0012–0085, FDA–1975–N–0012–0087, FDA–1975–N–0012–0088, FDA–1975–N–0012–0089, FDA–1975–N–0012–0090, FDA–1975–N–0012–0091, FDA–1975–N–0012–0093, FDA–1975–N–0012–0094, FDA–1975–N–0012–0095, FDA–1975–N–0012–0096, FDA–1975–N–0012–0097, FDA–1975–N–0012–0098, FDA–1975–N–0012–0099, FDA–1975–N–0012–0101, FDA–1975–N–0012–0105, FDA–1975–N–0012–0108, FDA–1975–N–0012–0109, FDA–1975–N–0012–0111, FDA–1975–N–0012–0110, FDA–1975–N–0012–0113, FDA–1975–N–0012–0116, FDA–1975–N–0012–0117, FDA–1975–N–0012–0118, FDA–1975–N–0012–0119, FDA–1975–N–0012–0121, FDA–1975–N–0012–0124, FDA–1975–N–0012–0126, FDA–1975–N–0012, FDA–1975–N–0012–0128, FDA–1975–N–0012–0132, FDA–1975–N–0012–0134, FDA–1975–N–0012–0135, FDA–1975–N–0012–0143, FDA–1975–N–0012–0148, FDA–1975–N–0012–0153, FDA–1975–N–0012–0154, FDA–1975–N–0012–0155, FDA–1975–N–0012–0157, FDA–1975–N–0012–0158, FDA–1975–N–0012–0161, FDA–1975–N–0012–0164, FDA–1975–N–0012–0166, FDA–1975–N–0012–0176, FDA–1975–N–0012–0177, FDA–1975–N–0012–0178, FDA–1975–N–0012–0184, FDA–1975–N–0012–0191, FDA–1975–N–0012–0198, FDA–1975–N–0012–0199, FDA–1975–N–0012–0200, FDA–1975–N–0012–0201, FDA–1975–N–0012–0202, FDA–1975–N–0012–0204, FDA–1975–N–0012–0206, FDA–1975–N–0012–0208, FDA–1975–N–0012–0209, FDA–1975–N–0012–0212, FDA–1975–N–0012–0213, FDA–1975–N–0012–0215, FDA–1975–N–0012–0217, FDA–1975–N–0012–0218, FDA–1975–N–0012–0219, FDA–1975–N–0012–0227, FDA–1975–N–0012–0233, FDA–1975–N–0012–0238, FDA–1975–N–0012–0241, FDA–1975–N–0012–0243, FDA–1975–N–0012–0258, FDA–1975–N–0012–0264, FDA–1975–N–0012–0266, FDA–1975–N–0012–0274, FDA–1975–N–0012–0275, FDA–1975–N–0012–0276, FDA–1975–N–0012–0281, FDA–1975–N–0012–0282, FDA–1975–N–0012–0284, FDA–1975–N–0012–0285, FDA–1975–N–0012–0286, FDA–1975–N–0012–0288.
13. Part 130-New Drugs, Procedures for Classification of Over-the-Counter Drugs, 37 FR 9464 (1972).
14. Comment No. FDA–1975–N–0012–0062 available at *http://www.regulations.gov.*
15. Comment No. FDA–1975–N–0012–0115 available at *http://www.regulations.gov.*
16. Comment No. FDA–1975–N–0012–0091 available at *http://www.regulations.gov.*
17. Comment No. FDA–1975–N–0012–0187 available at *http://www.regulations.gov.*
18. Comment No. FDA–1996–P–0205–0001 available at *http://www.regulations.gov.*
19. Comment No. FDA–1975–N–0012–0065 available at *http://www.regulations.gov.*
20. Comment No. FDA–1975–N–0012–0102 available at *http://www.regulations.gov.*
21. Comment No. FDA–1975–N–0012–0229 available at *http://www.regulations.gov.*
22. Centers for Disease Control and Prevention, "Clean Hands Save Lives: Emergency Situations," available at *http://emergency.cdc.gov/disasters/handhygienefacts.asp.*
23. National Institute of Allergy and Infectious Diseases, "Common Colds: Protect Yourself and Others," available at *http://www.niaid.nih.gov/topics/commoncold/Pages/default.aspx.*
24. "FDA Review of Clinical Outcome Studies in Consumer Use Settings," 2015, available at *http://www.regulations.gov* in Docket No. FDA–2016–N–0124.
25. Centers for Disease Control and Prevention, "Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force," *Morbidity and Mortality Weekly Report,* 51:1–45, 2002. Available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm.*
26. Mangram, A.J. et al., "Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee," *American Journal of Infection Control,* 27:97–132, 1999. Available at *http://www.sciencedirect.com/science/article/pii/S0196655399700088X.*
27. Larson, E., "Innovations in Health Care: Antisepsis as a Case Study," *American Journal of Public Health,* 79:92–99, 1989. available at *http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.79.1.92.*
28. FDA Review of Health Care Personnel Hand Wash Effectiveness Data, OTC Vol. 03HCATFM, available at *http://www.regulations.gov* in Docket No. FDA–2016–N–0101.
29. "Updated FDA Review of Antiseptic Hand Rubs Clinical Simulation Data," 2015, available at *http://www.regulations.gov* in Docket No. FDA–2016–N–0124.
30. "Briefing Material for the March 23, 2005, Meeting of the Nonprescription Drugs Advisory Committee," available at *http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4098B1_02_01-FDA-TOC.htm.*
31. Lennell, A. et al., "Alcohol-Based Hand-Disinfection Reduced Children's Absence From Swedish Day Care Centers," *Acta Paediatrica,* 97:1672–1680, 2008. Available at *http://onlinelibrary.wiley.com/doi/10.1111/j.1651-2227.2008.01057.x/epdf.*
32. Comments submitted in Docket No. FDA–1975–N–0012 available at *http://www.regulations.gov* with Comment Nos. FDA–1975–N–0012–0064, FDA–1975–N–0012–0071, FDA–1975–N–0012–0081, FDA–1975–N–0012–0082, FDA–1975–N–0012–0087, FDA–1975–N–0012–0088, and FDA–1975–N–0012–0096 in Docket No. FDA–1975–N–0012.
33. Comments submitted in Docket No. FDA–1975–N–0012 available at *http://www.regulations.gov* with Comment Nos. FDA–1975–N–0012–0073, FDA–1975–N–0012–0071, FDA–1975–N–0012–0075, FDA–1975–N–0012–0081, FDA–1975–N–0012–0085, FDA–1975–N–0012–0089, FDA–1975–N–0012–0093, FDA–1975–N–0012–0096, FDA–1975–N–0012–0105, FDA–1975–N–0012–0111, FDA–1975–N–0012–0108, FDA–1975–N–0012–0109, FDA–1975–N–0012–0113, FDA–1975–N–0012–0116, FDA–1975–N–0012–0117, FDA–1975–N–0012–0119, FDA–1975–N–0012–0128, FDA–1975–N–0012–0127, FDA–1975–N–0012–0153, FDA–1975–N–0012–0154, FDA–1975–N–0012–0155, FDA–1975–N–0012–0158, FDA–1975–N–0012–0157, FDA–1975–N–0012–0176, FDA–1975–N–0012–0177, FDA–1975–N–0012–0200, FDA–1975–N–0012–0201, FDA–1975–N–0012–0282, FDA–1975–N–0012–0275, FDA–1975–N–0012–0285, FDA–1975–N–0012–0286, FDA–1975–N–0012–0276, FDA–1975–N–0012–0288, FDA–1975–N–0012–0266, FDA–1975–N–0012–0164, FDA–1975–N–0012–0166, FDA–1975–N–0012–0184, FDA–1975–N–0012–0227, FDA–1975–N–0012–0194, FDA–1975–N–0012–0238, FDA–1975–N–0012–0037, FDA–1975–N–0012–0258, FDA–1975–N–0012–0124, FDA–1975–N–0012–0143, FDA–1975–N–0012–0160, FDA–1975–N–0012–0172, FDA–1975–N–0012–0264, FDA–1975–N–0012–0178, FDA–1975–N–0012–0191, FDA–1975–N–0012–0118, FDA–1975–N–0012–0121, FDA–1975–N–0012–0161, FDA–1975–N–0012–0198, FDA–1975–N–0012–0241, and FDA–1975–N–0012–0243 in Docket No. FDA–1975–N–0012.
34. Pandejpong, D. et al., "Appropriate Time-Interval Application of Alcohol Hand

Gel on Reducing Influenza-Like Illness Among Preschool Children: A Randomized, Controlled Trial," *American Journal of Infection Control,* 40:507–511, 2012. Available at *http://www.ajicjournal.org/article/S0196-6553(11)01137-0/pdf.*

35. Kampf, G., "Less And Less-Influence of Volume on Hand Coverage and Bactericidal Efficacy in Hand Disinfection," *BMC Infectious Diseases,* 13:472, 2013. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3851816/pdf/1471-2334-13-472.pdf.*
36. Kampf, G., "How Effective Are Hand Antiseptics for the Postcontamination Treatment of Hands When Used as Recommended?," *American Journal of Infection Control,* 36:356–360, 2008. Available at *http://www.ajicjournal.org/article/S0196-6553(07)00805-X/pdf.*
37. Macinga, D. R. et al., "Efficacy of Novel Alcohol-Based Hand Rub Products at Typical In-Use Volumes," *Infection Control Hospital Epidemiology,* 34:299–301, 2013. Available at *http://www.jstor.org/stable/10.1086/669514?seq=1#page_scan_tab_contents.*
38. Kampf, G. et al., "Efficacy of Ethanol-Based Hand Foams Using Clinically Relevant Amounts: A Cross-Over Controlled Study Among Healthy Volunteers," *BMC Infectious Diseases,* 10:78, 2010. Available at *http://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-10-78.*
39. Edmonds, S.L. et al., "Comparative Efficacy of Commercially Available Alcohol-Based Hand Rubs and World Health Organization-Recommended Hand Rubs: Formulation Matters," *American Journal of Infection Control,* 40:521–525, 2012. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4180309/pdf/12879_2014_Article_3830.pdf.*
40. ICH, "Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals S1A," November 1995, available at *http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Safety/S1A/Step4/S1A_Guideline.pdf.*
41. FDA Draft Guidance for Industry, "Over-the-Counter Sunscreens: Safety and Effectiveness Data" November 2015, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM473464.pdf.*
42. Ahn, K.C. et al., "In Vitro Biologic Activities of the Antimicrobials Triclocarban, Its Analogs, and Triclosan in Bioassay Screens: Receptor-Based Bioassay Screens," *Environmental Health Perspective,* 116:1203–1210, 2008. Available at *http://ehp.niehs.nih.gov/wp-content/uploads/116/9/ehp.11200.pdf.*
43. Chen, J. et al., "Triclocarban Enhances Testosterone Action: A New Type of Endocrine Disruptor?," *Endocrinology,* 149:1173–1179, 2008. Available at *http://press.endocrine.org/doi/pdf/10.1210/en.2007-1057.*
44. Crofton, K.M. et al., "Short-Term In Vivo Exposure to the Water Contaminant Triclosan: Evidence for Disruption of Thyroxine," *Environmental Toxicology and Pharmacology,* 24:194–197, 2007. Available at *http://www.sciencedirect.com/science/article/pii/S1382668907000683.*
45. Gee, R.H. et al., "Oestrogenic and Androgenic Activity of Triclosan in Breast Cancer Cells," *Journal of Applied Toxicology,* 28:78–91, 2008. Available at *http://onlinelibrary.wiley.com/doi/10.1002/jat.1316/pdf.*
46. Jacobs, M.N., G.T. Nolan, and S.R. Hood, "Lignans, Bacteriocides and Organochlorine Compounds Activate the Human Pregnane X Receptor (PXR)," *Toxicology and Applied Pharmacology,* 209:123–133, 2005, available at *http://www.sciencedirect.com/science/journal/0041008X/209/2.*
47. Kumar, V., C. Balomajumder, and P. Roy, "Disruption of LH-Induced Testosterone Biosynthesis in Testicular Leydig Cells by Triclosan: Probable Mechanism of Action," *Toxicology,* 250:124–131, 2008. Available at *http://www.sciencedirect.com/science/article/pii/S0300483X08002850.*
48. Kumar, V. et al., "Alteration of Testicular Steroidogenesis and Histopathology of Reproductive System in Male Rats Treated With Triclosan," *Reproductive Toxicology,* 27:177–185, 2009. Available at *http://www.sciencedirect.com/science/article/pii/S089062380800364X.*
49. Paul, K.B. et al., "Short-Term Exposure to Triclosan Decreases Thyroxine In Vivo via Upregulation of Hepatic Catabolism in Young Long-Evans Rats," *Toxicological Sciences,* 113:367–379, 2010. Available at *http://toxsci.oxfordjournals.org/content/113/2/367.full.pdf+html?sid=459e5732-786d-46ea-ab58-af2b9f517835.*
50. Stoker, T.E., E.K. Gibson, and L.M. Zorrilla, "Triclosan Exposure Modulates Estrogen-Dependent Responses in the Female Wistar Rat," *Toxicological Sciences,* 117:45–53, 2010. Available at *http://toxsci.oxfordjournals.org/content/117/1/45.full.pdf+html?sid=44df51a6–52c0-43cc-a629-e609dd1f2b64.*
51. Zorrilla, L.M. et al., "The Effects of Triclosan on Puberty and Thyroid Hormones in Male Wistar Rats," *Toxicological Sciences,* 107:56–64, 2009. Available at *http://toxsci.oxfordjournals.org/content/107/1/56.full.pdf+html?sid=f797a245-5b8c-413a-a124-1274d1a0b704.*
52. Anway, M.D. and M.K. Skinner, "Epigenetic Transgenerational Actions of Endocrine Disruptors," *Endocrinology,* 147:S43–49, 2006. Available at *http://press.endocrine.org/doi/pdf/10.1210/en.2005-1058.*
53. Bernal, A.J. and R.L. Jirtle, "Epigenomic Disruption: The Effects of Early Developmental Exposures," *Birth Defects Research (Part A),* 88:938–944, 2010. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2945443/pdf/nihms-208619.pdf.*
54. Alexander, E.K. et al., "Timing and Magnitude of Increases in Levothyroxine Requirements During Pregnancy in Women With Hypothyroidism," *New England Journal of Medicine,* 351:241–249, 2004. Available at *http://www.nejm.org/doi/pdf/10.1056/NEJMoa040079.*
55. Mitchell, M.L. and R.Z. Klein, "The Sequelae of Untreated Maternal Hypothyroidism," *European Journal of Endocrinology,* 151 Suppl 3:U45–48, 2004. Available at *http://www.eje-online.org/content/151/Suppl_3/U45.long.*
56. Pop, V.J. et al., "Low Maternal Free Thyroxine Concentrations During Early Pregnancy Are Associated with Impaired Psychomotor Development in Infancy," *Clinical Endocrinology,* 50:149–155, 1999. Available at *http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2265.1999.00639.x/abstract;jsessionid=8431812FC9630BDCE97AB0386480A87C.f03t01.*
57. ICH, "Testing for Carcinogenicity of Pharmaceuticals S1B," July 1997, available at *http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Safety/S1B/Step4/S1B_Guideline.pdf.*
58. FDA Guidance for Industry, "S7A Safety Pharmacology Studies for Human Pharmaceuticals," July 2001, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm074959.pdf.*
59. ICH, "Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility S5(R2)," November 2005, available at *http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Safety/S5_R2/Step4/S5_R2_Guideline.pdf.*
60. FDA Guidance for Industry, "S1C(R2) Dose Selection for Carcinogenicity Studies (Revision 1)," September 2008, available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*
61. FDA Guidance for Industry, "M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (Revision 1)," January 2010, available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*
62. FDA Draft Guidance for Industry, "Acne Vulgaris: Developing Drugs for Treatment," September 2005, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071292.pdf.*
63. FDA Guidance for Industry, "Nonclinical Evaluation of Endocrine-Related Drug Toxicity," September 2015, available at *http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm369043.pdf.*
64. FDA, "Guideline for the Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application," February 1987, available at *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm072112.pdf*
65. Bashaw, E.D. et al., "Maximal Usage Trial: An Overview of the Design of

Systemic Bioavailability Trial for Topical Dermatological Products," *Therapeutic Innovation and Regulatory Science,* 2014. Available at *http://dij.sagepub.com/content/49/1/108.full.pdf+html.*

66. Kinnula, S. et al., "Safety of Alcohol Hand Gel Use Among Children and Personnel at a Child Day Care Center," *American Journal of Infection Control,* 37:318–321, 2009. Available at *http://www.ajicjournal.org/article/S0196-6553(08)00698-6/pdf.*
67. FDA draft guidance for industry, "Bioanalytical Method Validation," (Revision 1), September 2013 available at *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm368107.pdf.*
68. Chuanchuen, R. et al., "Cross-Resistance Between Triclosan and Antibiotics in *Pseudomonas aeruginosa* Is Mediated by Multidrug Efflux Pumps: Exposure of a Susceptible Mutant Strain to Triclosan Selects *nfxB* Mutants Overexpressing MexCD-OprJ," *Antimicrobial Agents and Chemotherapy,* 45:428–432, 2001. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC90308/.*
69. Karatzas, K.A. et al., "Prolonged Treatment of *Salmonella enterica* serovar Typhimurium With Commercial Disinfectants Selects for Multiple Antibiotic Resistance, Increased Efflux and Reduced Invasiveness," *Journal of Antimicrobial Chemotherapy,* 60:947–955, 2007. Available at *http://jac.oxfordjournals.org/content/60/5/947.full.pdf.*
70. McMurry, L.M., M. Oethinger, and S.B. Levy, "Overexpression of *marA, soxS,* or *acrAB* Produces Resistance to Triclosan in Laboratory and Clinical Strains of *Escherichia coli," FEMS Microbiology Letters,* 166:305–309, 1998. Available at *http://onlinelibrary.wiley.com/doi/10.1111/j.1574-6968.1998.tb13905.x/pdf.*
71. Sanchez, P., E. Moreno, and J.L. Martinez, "The Biocide Triclosan Selects *Stenotrophomonas maltophilia* Mutants That Overproduce the SmeDEF Multidrug Efflux Pump," *Antimicrobial Agents and Chemotherapy,* 49:781–782, 2005. Available at *http://aac.asm.org/content/49/2/781.full.pdf+html.*
72. Tabak, M. et al., "Effect of Triclosan on *Salmonella typhimurium* at Different Growth Stages and in Biofilms," *FEMS Microbiology Letters,* 267:200–206, 2007. Available at *http://onlinelibrary.wiley.com/doi/10.1111/j.1574-6968.2006.00547.x/epdf.*
73. Srinivasan, V.B. et al., "Role of Novel Multidrug Efflux Pump Involved in Drug Resistance in *Klebsiella pneumoniae," PLoS One,* 9:e96288, 2014. Available at *http://journals.plos.org/plosone/article/asset?id=10.1371%2Fjournal.pone.0096288.PDF.*
74. Levy, S.B., "Active Efflux, A Common Mechanism for Biocide and Antibiotic Resistance," *Journal of Applied Microbiology Symposium Supplement,* 92:65S–71S, 2002. Available at *http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2672.92.5s1.4.x/epdf.*
75. Russell, A.D., "Do Biocides Select for Antibiotic Resistance?," *Journal of Pharmacy and Pharmacology,* 52:227–233, 2000. Available at *http://onlinelibrary.wiley.com/doi/10.1211/0022357001773742/epdf.*
76. Yazdankhah, S.P. et al., "Triclosan and Antimicrobial Resistance in Bacteria: An Overview," *Microbial Drug Resistance,* 12:83–90, 2006. Available at *http://online.liebertpub.com/doi/pdf/10.1089/mdr.2006.12.83.*
77. Martinez, J.L., "The Role of Natural Environments in the Evolution of Resistance Traits in Pathogenic Bacteria," *Proceedings in Biological Science,* 276:2521–2530, 2009. Available at *http://rspb.royalsocietypublishing.org/content/276/1667/2521.*
78. Nguyen, M. and G. Vedantam, "Mobile Genetic Elements in the Genus *Bacteroides,* and Their Mechanism(s) of Dissemination," *Mobile Genetic Elements,* 1:187–196, 2011. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312300/pdf/mge0103_0187.pdf.*
79. Cha, J. and A.M. Cupples, "Detection of the Antimicrobials Triclocarban and Triclosan in Agricultural Soils Following Land Application of Municipal Biosolids," *Water Research,* 43:2522–2530, 2009. Available at *http://www.sciencedirect.com/science/article/pii/S0043135409001456.*
80. Kolpin, D.W. et al., "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance," *Environmental Science and Technology,* 36:1202–1211, 2002. Available at *http://pubs.acs.org/doi/pdf/10.1021/es011055j.*
81. Russell, A.D. and G. McDonnell, "Concentration: A Major Factor in Studying Biocidal Action," *Journal of Hospital Infection,* 44:1–3, 2000. Available at *http://www.sciencedirect.com/science/article/pii/S0195670199906540.*
82. Beskitt, J.L. and J.D. Sun, "In Vitro Skin Penetration Characteristics of Ethanol in the Rabbit, Mouse, Rat, and Human," *Journal of Toxicology—Cutaneous and Ocular Toxicology,* 16:61–75, 1997. Available at *http://www.tandfonline.com/doi/abs/10.3109/15569529709048888.*
83. Behl, C.R. et al., "Hydration and Percutaneous Absorption: I. Influence of Hydration on Alkanol Permeation Through Hairless Mouse Skin," *Journal of Investigative Dermatology,* 75:346–352, 1980. Available at *http://www.sciencedirect.com/science/article/pii/S0022202X15459317.*
84. Durrheim, H. et al., "Permeation of Hairless Mouse Skin I: Experimental Methods and Comparison With Human Epidermal Permeation by Alkanols," *Journal of Pharmaceutical Sciences,* 69:781–786, 1980. Available at *http://www.sciencedirect.com/science/article/pii/S0022354915432745.*
85. Behl, C.R. et al., "Hydration and Percutaneous Absorption III: Influences of Stripping and Scalding on Hydration Alteration of the Permeability of Hairless Mouse Skin to Water and n-Alkanols," *Journal of Pharmaceutical Sciences,* 71:229–234, 1982. Available at *http://www.sciencedirect.com/science/article/pii/S0022354915440456.*
86. Flynn, G.L., H. Durrheim, and W.I. Higuchi, "Permeation of Hairless Mouse Skin II: Membrane Sectioning Techniques and Influence on Alkanol Permeabilities," *Journal of Pharmaceutical Sciences,* 70:52–56, 1981. Available at *http://www.sciencedirect.com/science/article/pii/S0022354915435336.*
87. National Toxicology Program, "TR 478: Toxicology and Carcinogenesis Studies of Diethanolamine in F344/N Rats and B6C3F1 Mice," 1999 available at *http://www.ncbi.nlm.nih.gov/pubmed/12571685.*
88. National Toxicology Program, "NTP Toxicology and Carcinogenesis Studies of Benzethonium Chloride (CAS No. 121–54–0) in F344/N Rats and B6C3F1 Mice (Dermal Studies)," *National Toxicology Program Technical Report Series,* 438:1–220, 1995 available at *http://www.ncbi.nlm.nih.gov/pubmed/12595925.*
89. Stenback, F., "The Tumorigenic Effect of Ethanol," *Acta Pathologica, Microbiologica, et Immunologica Scandinavica,* 77:325–326, 1969. Available at *http://onlinelibrary.wiley.com/doi/10.1111/apm.1969.77.issue-2/issuetoc.*
90. World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 96, Alcohol Consumption and Ethyl Carbamate," 2010. Available at *http://monographs.iarc.fr/ENG/Monographs/vol96/mono96.pdf.*
91. National Toxicology Program, "NTP Technical Report on the Toxicology and Carcinogenesis Studies of Urethane, Ethanol, and Urethane/Ethanol in B6C3F$_1$ Mice," August 2004, available at *http://www.ncbi.nlm.nih.gov/pubmed/16835633.*
92. Watabiki, T. et al., "Long-Term Ethanol Consumption in ICR Mice Causes Mammary Tumor in Females and Liver Fibrosis in Males," *Alcoholism, Clinical and Experimental Research,* 24:117S–122S, 2000. Available at *http://europepmc.org/abstract/MED/10803793.*
93. Soffritti, M.F. et al., "Results of Long-Term Experimental Studies on the Carcinogenicity of Methyl Alcohol and Ethyl Alcohol in Rats," *Annals of the New York Academy of Science,* 982:46–69, 2003. Available at *http://onlinelibrary.wiley.com/doi/10.1111/j.1749-6632.2002.tb04924.x/epdf.*
94. Centers for Disease Control and Prevention, "Alcohol Use in Pregnancy," Updated April 17, 2014, available at *http://www.cdc.gov/ncbddd/fasd/alcohol-use.html.*
95. National Institute on Alcohol Abuse and Alcoholism,"Fetal Alcohol Exposure," 2015, available at *http://*

pubs.niaaa.nih.gov/publications/FASDFactsheet/FASDfact.htm.

96. Karl, P.I. and S.E. Fisher, "Ethanol Alters Hormone Production in Cultured Human Placental Trophoblasts," *Alcoholism, Clinical and Experimental Research,* 17:816–821, 1993. Available at *http://onlinelibrary.wiley.com/doi/10.1111/j.1530-0277.1993.tb00847.x/epdf.*
97. Santucci, L., T.J. Graham, and D.H. Van Thiel, "Inhibition of Testosterone Production by Rat Leydig Cells With Ethanol and Acetaldehyde: Prevention of Ethanol Toxicity with 4-methylpyrazole," *Alcoholism, Clinical and Experimental Research,* 7:135–139, 1983. Available at *http://onlinelibrary.wiley.com/doi/10.1111/j.1530-0277.1983.tb05426.x/epdf.*
98. Salonen, I., P. Pakarinen, and I. Huhtaniemi, "Effect of Chronic Ethanol Diet on Expression of Gonadotropin Genes in the Male Rat," *Journal of Pharmacology and Experimental Therapeutics,* 260:463–467, 1992. Available at *http://jpet.aspetjournals.org/content/260/2/463.long.*
99. Emanuele, N. and M.A. Emanuele, "The Endocrine System: Alcohol Alters Critical Hormonal Balance," *Alcohol Health and Research World,* 21:53–64, 1997. Available at *http://www.ncbi.nlm.nih.gov/pubmed/15706763?dopt=Abstract.*
100. Heller, M. and L. Burd, "Review of Ethanol Dispersion, Distribution, and Elimination From the Fetal Compartment," *Birth Defects Research (Part A),* 100:277–283, 2014. Available at *http://onlinelibrary.wiley.com/doi/10.1002/bdra.23232/full.*
101. Paintner, A., A.D. Williams, and L. Burd, "Fetal Alcohol Spectrum Disorders—Implications for Child Neurology, Part 1: Prenatal Exposure and Dosimetry," *Journal of Child Neurology,* 27:258–263, 2012. Available at *http://jcn.sagepub.com/content/27/2/258.full.pdf+html.*
102. Little, P.J., M.L. Adams, and T.J. Cicero, "Effects of Alcohol on the Hypothalamic-Pituitary-Gonadal Axis in the Developing Male Rat," *Journal of Pharmacology and Experimental Therapeutics,* 263:1056–1061, 1992. Available at *http://jpet.aspetjournals.org/content/263/3/1056.long.*
103. Ali, Y. et al., "Alcohols" in *Disinfection, Sterilization, and Preservation,* Fifth ed., Lippincott Williams and Wilkins, Philadelphia, PA, 229–254, 2001. Available at *https://books.google.com/books?id=3f-kPJ17_TYC&printsec=frontcover&source=gbs_ViewAPI#v=onepage&q&f=false.*
104. Kampf, G. and A. Kramer, "Epidemiologic Background of Hand Hygiene and Evaluation of the Most Important Agents for Scrubs and Rubs," *Clinical Microbiology Reviews,* 17:863–893, 2004. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC523567/pdf/0085-03.pdf.*
105. McDonnell, G.E., "Alcohols" in *Antisepsis, Disinfection, and Sterilization—Types, Action, and Resistance,* ed., ASM Press, Washington, DC, 90–92, 2007.
106. Rutala, W.A., D.J. Weber, and Healthcare Infection Control Practices Advisory Committee (HICPAC), "Guideline for Disinfection and Sterilization in Healthcare Facilities," 2008, available at *http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf.*
107. Bevan, R.J. et al., "An Assessment of Potential Cancer Risk Following Occupational Exposure to Ethanol," *Journal of Toxicology and Environmental Health, Part B,* 12:188–205, 2009. Available at *http://www.tandfonline.com/doi/pdf/10.1080/10937400902894160.*
108. Cosmetic Ingredient Review, "Final Report on the Safety Assessment of Benzalkonium Chloride," *Journal of American College of Toxicology,* 8:589–625, 1989.
109. U.S. Environmental Protection Agency, "Reregistration Eligibility Decision for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)," August 2006, available at *http://nepis.epa.gov/EPA/html/DLwait.htm?url=/Exe/ZyPDF.cgi/P1005J4P.PDF?Dockey=P1005J4P.PDF.*
110. Comment No. FDA–1975–N–0012–0622 available at *http://www.regulations.gov.*
111. Comment No. FDA–1975–N–0012–0623 available at *http://www.regulations.gov.*
112. Comment No. FDA–1975–N–0012–0624 available at *http://www.regulations.gov.*
113. Comment No. FDA–1975–N–0012–0625 available at *http://www.regulations.gov.*
114. Comment No. FDA–1975–N–0012–0626 available at *http://www.regulations.gov.*
115. Comment No. FDA–1975–N–0012–0627 available at *http://www.regulations.gov.*
116. Comment No. FDA–1975–N–0012–0628 available at *http://www.regulations.gov.*
117. Comment No. FDA–1975–N–0012–0629 available at *http://www.regulations.gov.*
118. Comment No. FDA–1975–N–0012–0630 available at *http://www.regulations.gov.*
119. Comment No. FDA–1975–N–0012–0631 available at *http://www.regulations.gov.*
120. Comment No. FDA–1975–N–0012–0632 available at *http://www.regulations.gov.*
121. Comment No. FDA–1975–N–0012–0633 available at *http://www.regulations.gov.*
122. Braoudaki, M. and A.C. Hilton, "Adaptive Resistance to Biocides in *Salmonella enterica* and *Escherichia coli* O157 and Cross-Resistance to Antimicrobial Agents," *Journal of Clinical Microbiology,* 42:73–78, 2004. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC321691/pdf/0976.pdf.*
123. Lambert, R.J., J. Joynson, and B. Forbes, "The Relationships and Susceptibilities of Some Industrial, Laboratory and Clinical Isolates of *Pseudomonas aeruginosa* to Some Antibiotics and Biocides," *Journal of Applied Microbiology,* 91:972–984, 2001. Available at *http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2672.2001.01460.x/epdf.*
124. Langsrud, S., G. Sundheim, and A.L. Holck, "Cross-Resistance to Antibiotics of *Escherichia coli* Adapted to Benzalkonium Chloride or Exposed to Stress-Inducers," *Journal of Applied Microbiology,* 96:201–208, 2004. Available at *http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2672.2003.02140.x/epdf.*
125. Bore, E. et al., "Adapted Tolerance to Benzalkonium Chloride in *Escherichia coli* K–12 Studied by Transcriptome and Proteome Analyses," *Microbiology,* 153:935–946, 2007. Available at *https://www.researchgate.net/publication/6427071_Bore_E_et_al_Adapted_tolerance_to_benzalkonium_chloride_in_Escherichia_coli_K-12_studied_by_transcriptome_and_proteome_analyses_Microbiology_153_935-946.*
126. Chuanchuen, R. et al., "Susceptibilities to Antimicrobials and Disinfectants in Salmonella Isolates Obtained From Poultry and Swine in Thailand," *Journal of Veterinary Medical Science,* 70:595–601, 2008. Available at *https://www.jstage.jst.go.jp/article/jvms/70/6/70_6_595/_pdf.*
127. Lear, J.C. et al., "Chloroxylenol- and Triclosan-Tolerant Bacteria From Industrial Sources—Susceptibility to Antibiotics and Other Biocides," *International Biodeterioration and Biodegradation,* 57:51–56, 2006. Available at *http://ac.els-cdn.com/S096483050500137X/1-s2.0-S096483050500137X-main.pdf?_tid=67672f92-2b57-11e6-8f11-00000aacb35e&acdnat=1465156688_42b5bfa1b42253d87614efd8e6e6f809*
128. Loughlin, M.F., M.V. Jones, and P.A. Lambert, "*Pseudomonas aeruginosa* Cells Adapted to Benzalkonium Chloride Show Resistance to Other Membrane-Active Agents But Not to Clinically Relevant Antibiotics," *Journal of Antimicrobial Chemotherapy,* 49:631–639, 2002. Available at *https://jac.oxfordjournals.org/content/49/4/631.full.pdf.*
129. Joynson, J.A., B. Forbes, and R.J. Lambert, "Adaptive Resistance to Benzalkonium Chloride, Amikacin and Tobramycin: The Effect on Susceptibility to Other Antimicrobials," *Journal of Applied Microbiology,* 93:96–107, 2002. Available at *http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2672.2002.01667.x/epdf.*
130. Bates, H.K. et al., "Developmental Neurotoxicity Evaluation of Orally Administered Isopropanol in Rats," *Fundamental and Applied Toxicology,* 22:152–158, 1994. Available at *http://www.sciencedirect.com/science/article/pii/S0272059084710189.*
131. Faber, W.D., K.L. Pavkov, and R. Gingell, "Review of Reproductive and Developmental Toxicity Studies With Isopropanol," *Birth Defects Research Part B Developmental and Reproductive Toxicology,* 83:459–476, 2008. Available at *http://onlinelibrary.wiley.com/doi/10.1002/bdrb.20167/full.*
132. Lehman, A.J., H. Schwerma, and E. Rickards, "Isopropyl Alcohol: Acquired Tolerance in Dogs, Rate of Disappearance From the Blood Stream in Various Species, and Effects on Successive

Generation of Rats," *Journal of Pharmacology and Experimental Therapeutics,* 85:61–69, 1945. Available at *http://jpet.aspetjournals.org/content/85/1/61.full.pdf+html.*

133. Nelson, B.K. et al., "Teratogenicity of n-Propanol and Isopropanol Administered at High Inhalation Concentrations to Rats," *Food and Chemical Toxicology,* 26:247–254, 1988. Available at *http://www.sciencedirect.com/science/article/pii/027869158890126 3.*
134. Tyl, R.W. et al., "Developmental Toxicity Evaluation of Isopropanol by Gavage in Rats and Rabbits," *Fundamental and Applied Toxicology,* 22:139–151, 1994. Available at *http://toxsci.oxfordjournals.org/content/22/1/139.full.pdf+html.*
135. Bevan, C. et al., "Two Generation Reproductive Toxicity Study with Isopropanol in Rats," *Journal of Applied Toxicology,* 15:117–123, 1995. Available at *http://onlinelibrary.wiley.com/doi/10.1002/jat.2550150210/epdf.*
136. McEvoy, E.M., P.C. Wright, and M.T. Bustard, "The Effect of High Concentration Isopropanol on the Growth of a Solvent-Tolerant Strain of *Chlorella vulgaris," Enzyme and Microbial Technology,* 35:140–146, 2004. Available at *http://ac.els-cdn.com/S0141022904001085/1-s2.0-S0141022904001085-main.pdf?_tid=b24dcd2a-2b59-11e6-9e77-00000aab0f02&acdnat=1465157672_20da9f1e4b98722e189e8520c5050c00.*
137. Geng, Y. et al., "Biodegradation of Isopropanol by a Solvent-Tolerant *Paracoccus denitrificans* Strain," *Preparative Biochemistry and Biotechnology,* 45:491–499, 2015. Available at *http://www.tandfonline.com/doi/full/10.1080/10826068.2014.923452.*
138. Bustard, M.T. et al., "Biodegradation of High-Concentration Isopropanol by a Solvent-Tolerant Thermophile, *Bacillus pallidus," Extremophiles,* 6:319–323, 2002. Available at *https://www.researchgate.net/publication/11173057_Biodegradation_of_high-concentration_isopropanol_by_a_solvent-tolerant_thermophile_Bacillus_pallidus_Extremophiles.*
139. Kirschner, M.H. et al., "Transdermal Resorption of an Ethanol- and 2-Propanol-Containing Skin Disinfectant," *Langenbeck's Archives of Surgery.,* 394:151–157, 2009. Available at *http://www.springer.com/medicine/surgery/journal/423.*
140. Turner, P., B. Saeed, and M.C. Kelsey, "Dermal Absorption of Isopropyl Alcohol From a Commercial Hand Rub: Implications for its Use in Hand Decontamination," *The Journal of Hospital Infection,* 56:287–290, 2004. Available at *http://www.sciencedirect.com/science/article/pii/S0195670104000131.*
141. Below, H. et al., "Dermal and Pulmonary Absorption of Propan-1-ol and Propan-2-ol From Hand Rubs," *American Journal of Infection Control,* 40:250–257, 2012. Avilable at *http://www.ajicjournal.org/article/S0196–6553(11)00227-6/pdf.*
142. Puschel, K., "Percutaneous Alcohol Intoxication," *European Journal of Pediatrics,* 136:317–318, 1981.
143. Dhillon, S., "Toxicology Updates-Isopropanol," *Journal of Applied Toxicology,* 15:501–506, 1995. Available at *http://onlinelibrary.wiley.com/doi/10.1002/jat.2550150612/epdf.*
144. International Programme on Chemical Safety, "2-Propanol," 1990, available at *http://www.inchem.org/documents/ehc/ehc/ehc103.htm#SectionNumber%3A8.3.*
145. Boatman, R.J. et al., "Dermal Absorption and Pharmacokinetics of Isopropanol in the Male and Female F–344 Rat," Drug Metabolism and Disposition," *Drug Metabolism and Disposition,* 26:197–202, 1998. Available at *http://dmd.aspetjournals.org/content/26/3/197.full.pdf+html.*
146. Martinez, T.T. et al., "A Comparison of the Absorption and Metabolism of Isopropyl Alcohol by Oral, Dermal and Inhalation Routes," *Veterinary and Human Toxicology,* 28:233–236, 1986. Available at *http://europepmc.org/abstract/med/3727356.*
147. Slauter, R.W. et al., "Disposition and Pharmacokinetics of Isopropanol in F–344 Rats and B6C3F1 Mice," *Fundamental and Applied Toxicology,* 23:407–420, 1994. Available at *http://toxsci.oxfordjournals.org/content/23/3/407.full.pdf.*
148. Kapp, R.W., Jr. et al., "Isopropanol: Summary of TSCA Test Rule Studies and Relevance to Hazard Identification," *Regulatory Toxicology and Pharmacology,* 23:183–192, 1996. Available at *http://www.sciencedirect.com/science/article/pii/S0273230096900422.*
149. WHO International Program on Chemical Safety Working Group, "2-Propanol," *Environmental Health Criteria,* 103:132, 1990. Available at *http://www.inchem.org/documents/ehc/ehc/ehc103.htm#SectionNumber:8.3.*
150. World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide," 71 (part 3):1027–1036, 1999, available at *http://monographs.iarc.fr/ENG/Monographs/vol71/mono71.pdf.*
151. Burleigh-Flayer, H. et al., "Isopropanol Vapor Inhalation Oncogenicity Study in Fischer 344 Rats and CD–1 Mice," *Fundamental and Applied Toxicology,* 36:95–111, 1997. Available at *http://www.sciencedirect.com/science/article/pii/S0272059096922848.*

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310, as proposed to be amended December 17, 2013, at 78 FR 76444, and May 1, 2015, at 80 FR 25166, is proposed to be further amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 360hh-360ss, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.545:

■ a. Add paragraph (a)(27)(v);

■ b. In paragraph (d) introductory text, remove "(d)(42)" and in its place add "(d)(43)"; and

■ c. Add paragraph (d)(43).

The additions to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(27) * * *

(v) *Consumer antiseptic rub drug products.* Approved as of [DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**]:

Alcohol (ethanol and ethyl alcohol)
Benzalkonium chloride
Isopropyl alcohol

* * * * *

(d) * * *

(43) [DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], for products subject to paragraph (a)(27)(v) of this section.

Dated: June 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15410 Filed 6–29–16; 8:45 am]

BILLING CODE 4164–01–P

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1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 126 June 30, 2016

Part V

Environmental Protection Agency

40 CFR Parts 60 and 62
Clean Energy Incentive Program Design Details; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 62

[EPA–HQ–OAR–2016–0033; FRL–9945–01–OAR]

RIN 2060–AS84

Clean Energy Incentive Program Design Details

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is proposing design details of the Clean Energy Incentive Program (CEIP). The CEIP is a program that states have the option to adopt if they wish to incentivize certain early emission reduction projects under the Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units (also known as the Clean Power Plan Emission Guidelines (EGs)). The framework for the CEIP was established in the Clean Power Plan EGs, where the EPA also noted that the design details of the program would be developed in a follow-on action. This proposal addresses those design details. In addition, we are re-proposing the CEIP-related aspects of the proposed rate-based and mass-based model trading rules—referred to in this action as optional example regulatory text. This proposal is consistent with the Supreme Court's orders staying the Clean Power Plan during judicial review. The timing elements of the CEIP may be adjusted, if necessary, upon resolution of the petitions for review of the Clean Power Plan.

DATES: *Comments.* Comments must be received on or before August 29, 2016.

Public Hearing. The EPA will hold one public hearing on the CEIP design details proposed rule. The hearing will be held to accept oral comments on the proposal. The hearing will be held in Chicago, Illinois, on August 3, 2016. The hearing will begin at 9:00 a.m. Central Standard Time CST and will conclude at 8:00 p.m. (CST). There will be a lunch break from 12:00 p.m. to 1:00 p.m. and a dinner break from 5:00 p.m. to 6:00 p.m.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2016–0033, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Instructions. Direct your comments on the CEIP Design Details proposed rule to Docket ID No. EPA–HQ–OAR–2016–0033. The EPA's policy is that all comments received will be included in the public docket and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket. The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2016–0033. The EPA has previously established a docket for the June 18, 2014, Clean Power Plan proposal under Docket ID No. EPA–HQ–OAR–2013–0602. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the EPA Docket Center (EPA/DC), EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

Public Hearing. The hearing will be held in Chicago, Illinois, on August 3, 2016; in the Lake Michigan Room, Ralph Metcalfe Federal Building, 77 West Jackson Boulevard. The hearing will begin at 9:00 a.m. Central Standard Time CST and will conclude at 8:00 p.m. (CST). There will be a lunch break from 12:00 p.m. to 1:00 p.m. and a dinner break from 5:00 p.m. to 6:00 p.m.

To register to speak at the hearing, please use the online registration form available at *http://www.epa.gov/cleanpowerplan/clean-energy-incentive-program* or please contact Ms. Pamela Garrett at (919) 541–7966 or send an email to *publichearing@epa.gov.* The last day to pre-register to speak at the hearing will be Monday, August 1, 2016. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk, although preferences on speaking times may not be able to be fulfilled. Please note that registration requests received before the hearing will be confirmed by the EPA via email. We cannot guarantee that we can accommodate all timing requests and will provide requestors with the next available speaking time in the event that their requested time is taken. Please note that the time outlined in the confirmation email received will be the scheduled speaking time. Again, depending on the flow of the day, times may fluctuate. If you require the service of a translator or special accommodations such as audio description, we ask that you pre-register for the hearing by Friday, July 22, 2016, as we may not be able to arrange such accommodations without advance notice. Please note that any updates made to any aspect of the hearing will be posted online at *http://www.epa.gov/cleanpowerplan.www.epa.gov/cleanpowerplan.* While the EPA expects the hearing to go forward as set forth previously, we ask that you monitor our Web site or contact Ms. Pamela Garrett at (919) 541–7966 or at *garrett.pamela@epa.gov* to determine if there are any updates to the information on the hearings. The EPA does not intend to publish a notice in the **Federal Register** announcing any such updates.

The hearing will provide interested parties the opportunity to present data, views, or arguments concerning the proposed action. The EPA will make every effort to accommodate all speakers who wish to register to speak at the hearing venue on the day of the hearing. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing. Verbatim transcripts of the hearing and written statements will be included in the docket for the rulemaking. The EPA plans for the hearing to run on schedule; however, due to on-site schedule fluctuations, actual speaking times may shift slightly.

Because this hearing will be held at a U.S. government facility, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. Please note that the REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. If your driver's license is issued by American Samoa, Illinois, Minnesota, Missouri, New Mexico, or the state of Washington, you must present an additional form of identification to enter the federal building. Acceptable alternative forms of identification include: Federal employee badges, passports, enhanced driver's licenses, and military identification cards. In addition, you will need to obtain a property pass for any personal belongings you bring with you. Upon leaving the building, you will be required to return this property pass to the security desk. No large signs will be allowed in the building, cameras may only be used outside of the building, and demonstrations will not be allowed on federal property for security reasons.

Attendees will be asked to go through metal detectors. To help facilitate this process, please be advised that you will be asked to remove all items from all pockets and place them in provided bins for screening; remove laptops, phones, or other electronic devices from their carrying case and place in provided bins for screening; avoid shoes with metal shanks, toe guards, or supports as a part of their construction; remove any metal belts, metal belt buckles, large jewelry, watches and follow the instructions of the guard if identified for secondary screening. Additionally, no weapons (*e.g.,* pocket knives) or drugs or drug paraphernalia (*e.g.,* marijuana) will be allowed in the building. We recommend that you arrive 20 minutes in advance of your speaking time to allow time to go through security and to check in with the registration desk.

FOR FURTHER INFORMATION CONTACT: Dr. Tina Ndoh, Sector Policies and Programs Division, Office of Air Quality Planning and Standards (D243–04), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2750; email address: *ndoh.tina@epa.gov.*

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

ARP—Acid Rain Program
BSER—Best system of emission reduction
CAA—Clean Air Act
CHP—Combined heat and power
CBI—Confidential business information
CEIP—Clean Energy Incentive Program
CST—Central Standard Time
CO_2—Carbon dioxide
CVR—Conservation Voltage Reduction
EE—Energy efficiency
EGs—Emission Guidelines
EGU—Electric generating unit
EJ—Environmental justice
EM&V—Evaluation, measurement, and verification
EPA—Environmental Protection Agency
ERC—Emission rate credit
FPLG—Federal Poverty Level Guidelines
HUD—Department of Housing and Urban Development
ITC—Investment Tax Credit
M&V—Monitoring and verification
MWh—Megawatt-hour
NMTC—New Market Tax Credits
NTTAA—National Technology Transfer and Advancement Act
OMB—Office of Management and Budget
PRA—Paperwork Reduction Act
PTC—Production Tax Credit
RE—Renewable energy
RFA—Regulatory Flexibility Act
TSD—Technical Support Document
TTN—Technology Transfer Network
UMRA—Unfunded Mandates Reform Act
U.S.—United States
WAP—Weatherization Assistance Program
WHP—Waste heat to power
WWW—World Wide Web

Organization of This Document. The information in this preamble is organized as follows:

I. General Information
  A. What should I consider as I prepare my comments for the EPA?
II. Background
  A. What is the framework for the CEIP that was established in the final Clean Power Plan Emission Guidelines?
  B. What are the statutory authorities for this action, including legal authority and basis for the CEIP?
  C. How does this action relate to the final Clean Power Plan and proposed federal plan and model trading rules?
  D. What key comments were received during the informal feedback process?
III. Clean Energy Incentive Program Design Details
  A. Provisions for Matching Allowances and ERCs To Be Issued by the EPA From the 300 Million Short Ton Pool
  B. Requirements for States That Choose To Participate in the CEIP
  C. Requirements for CEIP-Eligible Projects
  D. CEIP Participation for States, Tribes and Territories for Which the EPA Has Not Established Goals
IV. Community and Environmental Justice Considerations.
V. Statutory and Executive Order Reviews
  A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  B. Paperwork Reduction Act (PRA)
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  D. Unfunded Mandates Reform Act (UMRA)
  E. Executive Order 13132: Federalism
  F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  I. National Technology Transfer and Advancement Act (NTTAA)
  J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. What should I consider as I prepare my comments for the EPA?

Do not submit information that you consider to be CBI electronically through *http://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address: OAQPS Document Control Officer (Room C404 02), U.S. EPA, Research Triangle Park, NC 27711, Attention Docket ID No. EPA–HQ–OAR–2016–0033. Clearly mark the part or all of the information that you claim to be CBI. For CBI on a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

Docket. The docket number for the proposed action is Docket ID No. EPA–HQ–OAR–2016–0033.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of the proposed action is available on the Internet through the EPA's Technology Transfer Network (TTN) Web site, a forum for information and technology exchange in various areas of air pollution control. Following signature by the EPA Administrator, the EPA will post a copy of the proposed action at *http://www2.epa.gov/cleanpowerplan/regulatory-actions#regulations.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposed rule and key technical documents on the same Web site.

II. Background

A. What is the framework for the CEIP that was established in the final Clean Power Plan Emission Guidelines?

The CEIP is a program that states have the option to adopt if they wish to incentivize certain early emission reduction projects under the Carbon Pollution EGs for Existing Stationary Sources: Electric Utility Generating Units (also known as the Clean Power Plan EGs).[1] The EPA included the CEIP in the Clean Power Plan EGs in response to the many comments we received supporting the early action crediting concept we discussed in the Clean Power Plan proposed rule, *see* 79 FR 34918–34919 (June 18, 2014). Many stakeholders supported including a mechanism for recognizing early actions for the emission reductions they provide prior to the start of the performance period in 2022. The inclusion of the CEIP was also responsive to comments from stakeholders describing the disproportionate burdens that some communities already bear, and stating that all communities should have equal access to the benefits of clean and affordable energy. The CEIP framework provided in the final EGs offers a mechanism that enables states to incentivize early investments in wind and solar renewable energy (RE) generation,[2] as well as in demand-side energy efficiency (EE) projects in low-income communities that generate carbon-free megawatt hours (MWh) or reduce demand-side energy use during 2020 and/or 2021.[3]

In the final Clean Power Plan, the EPA finalized a requirement that states wishing to participate in the CEIP must indicate by September 6, 2016, at a minimum, their intention to participate in the CEIP. On February 9, 2016, the Supreme Court stayed the Clean Power Plan during the pendency of the litigation. As a result of the stay, states are not required to provide such notice by September 6, 2016. The EPA will provide further direction on submittal timing requirements, as well as any other adjustments in timing that may be needed, upon the resolution of the judicial petitions for review of the Clean Power Plan. We discuss in more detail the relationship of this action to the Supreme Court's stay in section II.C of this preamble. For purposes of this proposal, however, we will use the original dates in the Clean Power Plan and the CEIP, with the expectation that all timing issues will be dealt with upon the resolution of the litigation.

In the event that the EPA finalizes a federal plan for a state, it continues to be the EPA's intention that the CEIP will be available in that state. The EPA believes the optional example regulatory provisions we are proposing, as presumptively approvable for state use or adoption, could suitably function as the CEIP provisions in a potential federal plan. We solicit comments on this aspect of the proposal. However, the EPA will not promulgate a federal plan until some period of time after the petitions for review of the Clean Power Plan are resolved and the stay is lifted. The EPA lacks authority to promulgate a federal plan for a state in the absence of a finding by the Agency that a state has failed to submit a plan by a legal deadline or a final action disapproving a required state plan. During the pendency of the Supreme Court's stay, states are not obliged to submit plans and therefore the EPA could not take either such action or promulgate any final federal plan for any state under the Clean Power Plan EGs. As explained later in this action, there are also pathways whereby a state could implement the CEIP under a duly promulgated federal plan.

While the legal effectiveness of the Clean Power Plan is currently stayed, the EPA has determined that it is appropriate to move forward with the design details of the CEIP component of the Clean Power Plan at this time. States have the authority to continue moving forward on their own volition with the design of state plans, and the EPA retains the authority to continue working with states as they do so. For states that, at their own discretion, wish to continue plan development, this action will help them understand what must be included in a state plan if they wish to opt into the CEIP. In addition, the proposal is responsive to the states that requested EPA provide additional detail on the design details of the CEIP as soon as possible. The EPA acknowledged to the public in the October 23, 2015, notice of final rulemaking that it would need to take a future action on the CEIP because there are aspects of the CEIP that need to be completed in order for the program to be able to be implemented (80 FR 64830). Indeed, commenters on the model rules and federal plan proposal, including states, requested that the Agency expeditiously complete the design details of the CEIP. *See, e.g.,* Comment of Minnesota Public Utilities Commission (EPA–HQ–OAR–2015–0199–0363); Comment of Kyra L. Moore, Dir., State of Missouri Dep't of Natural Resources (EPA–HQ–OAR–2015–0199–0457); Hearing Testimony of Jeff Cappella, Western Clean Energy

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[1] The Clean Power Plan establishes carbon dioxide (CO_2) emission standards for electric utility generating Units (EGUs) in states and tribal areas that have such units (called affected EGUs). In the Clean Power Plan and in this rulemaking, the term "state" generally encompasses the 50 states and the District of Columbia, U.S. territories, and any Indian Tribe that has been approved by the EPA pursuant to 40 CFR 49.9 as eligible to develop and implement a Clean Air Act (CAA) section 111(d) plan. Tribes with affected EGUs may, but are not required to, submit tribal plans to implement the EGs. The EPA would not implement the EGs through a federal plan in a tribal area without first making a necessary or appropriate finding under section 301(d). In the context of the CEIP, the term "state" will usually refer only to those states or Indian country areas of the contiguous U.S. that have affected EGUs under the Clean Power Plan EGs. We discuss the role of states and tribes without affected EGUs in section III.D of this preamble.

[2] Currently, eligible RE technologies are limited to wind and solar resources. However, please note that the Agency is proposing a limited expansion of eligibility to certain other zero-emitting, renewable technologies. *See section III.C.4 of this preamble.*

[3] Currently, eligible low-income community projects are limited to demand-side EE. However, please note that the Agency is proposing a limited expansion of eligibility to include solar projects implemented to serve low-income communities that provide direct electricity bill benefits to low-income community ratepayers. *See section III.C.5 of this preamble.*

Campaign (November 16, 2015) (EPA–HQ–OAR–2015–0199–0233–A1–06). It is prudent to propose this action now in order to assist those states that have decided to move forward and who are contemplating participation in the CEIP, so that they have the requisite tools and information for doing so. While this proposal generally will be helpful to those who are interested in participating in the CEIP, because the CEIP is an optional program, relies on voluntary measures, and will not become available to the states until the stay is lifted, this proposal will not disadvantage any party (including those who have decided to await the resolution of the litigation prior to acting to develop their state plans). Finally, we heard from many stakeholders that they would like an opportunity to comment on a more developed proposal regarding CEIP topics; the EPA is responding to those requests by issuing this proposal, which provides a new opportunity to submit comments on the CEIP topics addressed here and to review actual proposed rule language. In order to ensure that the EPA considers and responds to your comments on these CEIP topics, you must submit your comments on this proposal, following the process explained in section I.B of this preamble.

The CEIP is an incentive program in which both the states, should they elect to participate, and the EPA play a role. The program operates by means of states allocating or issuing early action compliance instruments—called early action allowances or early action emission rate credits (ERCs)—which are then matched by EPA with additional compliance instruments—called matching allowances or matching ERCs. States in turn provide these awarded matching compliance instruments to the providers of eligible CEIP RE and low-income community projects that received the early action allowances or early action ERCs from the state.

The EPA designed the CEIP to be an implementable option for states using mass-based plans and states using rate-based plans. The final Clean Power Plan specified the number of early action ERCs that a state may award to CEIP-eligible project providers per MWh of generation or savings achieved in 2020 and/or 2021 under a rate-based plan, but stated that the EPA would speak to the award of early action allowances under a mass-based plan in a future action. Awards of early action ERCs, and the EPA's proposed approach for the award of early action allowances, are discussed in section III.A of this preamble.

In the final Clean Power Plan, the EPA stated that, in the case of eligible CEIP solar and wind projects,[4] for every two MWh of energy generation, the state will provide an award of one early action ERC for a state adopting a rate-based plan (or an appropriate commensurate number of early action allowances for states adopting a mass-based plan), and the EPA will provide an award of one matching ERC (or an appropriate commensurate number of matching allowances). Thus, the total award to each eligible wind and solar project is made on a one-to-one basis for every one MWh of clean generation (either one ERC or an appropriate commensurate number of allowances for every one MWh of clean generation). In the case of eligible CEIP demand-side EE projects in low-income communities,[5] for every two MWh of energy savings, the state will provide an award of two early action ERCs (or an appropriate commensurate number of early action allowances), and the EPA will provide an award of two matching ERCs (or an appropriate commensurate number of matching allowances). Thus, the total award for low-income EE projects is made on a two-to-one basis for every one MWh of energy savings (either two ERCs or an appropriate commensurate number of allowances for every one MWh of energy savings). *See* 80 FR 64831, October 23, 2015.

The overall size of the EPA matching pool available to all CEIP-participating states has been set at 300 million short tons of CO_2, and the EPA will award matching allowances or matching ERCs from this pool in an amount not to exceed in the aggregate this limit (80 FR 64829). The 300 million ton matching pool, referred to in this preamble as the "matching pool," will be apportioned among CEIP-participating states pro rata based on the amount of reductions from 2012 CO_2 emission levels the affected EGUs in each state are required to achieve relative to those in other CEIP-participating states.[6]

Eligible CEIP projects must be located in or benefit a state that has one or more affected EGUs with an approved final plan that includes requirements establishing its participation in the CEIP. For purposes of the CEIP, we propose that "benefit" a state means that the electricity is generated or saved with the intention to meet or reduce electricity demand in the CEIP-participating state.

Additionally, in the final Clean Power Plan, we stated that eligible projects must commence construction (in the case of solar and wind projects) or commence operations (in the case of low-income EE projects) following the submission of a final state plan, or September 6, 2018, for a state that chooses not to submit a final plan by that date. As discussed later in this preamble, we are proposing to adjust this timing requirement to remove final state plan submittal as a triggering event for eligibility.[7] In addition, the EPA did not define the terms "commence construction" or "commence operation" in regards to the CEIP in the final Clean Power Plan. In preparation for this action, we solicited public input on the appropriate definitions for these terms,[8] and we speak to those definitions in section III.C of this preamble.

A CEIP-participating state must include requirements in its plan for determining CEIP project eligibility and quantifying and verifying the MWh of generation or savings from an eligible project. These requirements must be consistent with the requirements included in the final Clean Power Plan EGs for the issuance of ERCs.[9] This includes requirements for demonstration of eligibility; evaluation, measurement, and verification (EM&V) plans; monitoring and verification (M&V) reports; and independent verification of project submittals. In addition, the state's plan must include a mechanism that ensures that the award of early action allowances or early action ERCs to CEIP-eligible parties will not impact the CO_2 emission performance of affected EGUs required to meet mass-based or rate-based CO_2 emission standards during the plan performance periods. This mechanism is not required to account for matching allowances or ERCs that may be issued to the state by the EPA.[10]

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[4] In this action, we are proposing a limited expansion of eligible RE resources to include geothermal and hydropower. See section III.C. of this action for additional discussion of the proposed limited RE expansion.

[5] In this action, we are proposing a limited expansion of eligible low-income community projects to include solar projects implemented to serve low-income communities in addition to demand-side EE projects. See section III.C. of this action for additional discussion of the expansion of eligible low-income community projects.

[6] See discussion of proposed apportionment method in section III.A *of this preamble.*

[7] We will continue to use September 6, 2018, as the putative eligibility start date under the CEIP for "commence operation" of low-income EE projects, while recognizing that in light of the Supreme Court's stay, this date, as well as the deadline for final state plan submittals, may need to be adjusted. The applicable eligibility date for "commence commercial operation," which the EPA is proposing would replace the term "commence construction" with regard to RE projects, is discussed in section III.C of this preamble.

[8] See Clean Energy Incentive Program Next Steps (October 21, 2015) at *http://www.epa.gov/sites/production/files/2015-10/documents/ceip_next_steps_10_21_15.pdf.*

[9] See 40 CFR 60.5805 through 60.5835.

B. What are the statutory authorities for this action, including legal authority and basis for the CEIP?

The CEIP is an optional component of the Clean Power Plan, and the Clean Power Plan is an exercise of the EPA's authority under section 111(d) of the CAA, 42 U.S.C. 7411(d). The legal authority and rationale supporting the Clean Power Plan are discussed in the final rulemaking and accompanying Legal Memorandum. *See, e.g.,* 80 FR 64662, 64707–64710 (October 23, 2015). The rationale and legal authority for the CEIP in particular are also set forth in the final Clean Power Plan. *Id.* 64831–64832. Nothing in this action reopens the legal determinations or rationale set forth in the final Clean Power Plan.[11]

The EPA established the CEIP in the final Clean Power Plan EGs, and took final action with respect to certain key design parameters for the program while identifying other details of the program that would be determined through a future action. *See* 80 FR 64829–64832 (October 23, 2015). The Agency discussed mechanisms for recognizing and providing incentives for early action in the Clean Power Plan proposal and requested comment on design elements of different approaches, see 79 FR 34830, 34918–34919 (June 18, 2014). The Agency identified additional considerations regarding approaches to incentivize early action in a notice of data availability on which the public also had an opportunity to comment, *see* 79 FR 64543, 64545–64546 (October 30, 2014). The EPA established the CEIP in the final Clean Power Plan in response to overwhelmingly supportive comments from the public that the EGs should provide a mechanism for incentivizing and recognizing early action. In this action, the EPA is not reopening its decision to establish the CEIP, the maximum size of the matching pool, the requirement for states to include a mechanism in their plans that ensures that the award of early action allowances or early action ERCs will not impact the CO_2 emission performance of affected EGUs required to meet CO_2 emission standards under the Clean Power Plan EGs, any other design parameters not expressly opened for comment or proposal in this document, or its determination of legal authority and rationale for the CEIP provided in the preamble to the final Clean Power Plan EGs, *see* 80 FR 64831–64832. Additional information on the relationship between this action and the EGs, as well as the proposed federal plan and model trading rules, is provided in section II.C of this preamble.

The CEIP is optional for states; states are not required to implement this incentive program for early action. However, if a state does choose to participate in the CEIP, it must follow the requirements specified in the final Clean Power Plan EGs as well as any additional requirements that may be finalized through this rulemaking action. Additionally, as discussed in section II.C of this preamble, in instances of federal plan promulgation, the EPA's intent is that the CEIP would also be available. Even in the case of a federal plan, states would have an ability to implement the CEIP, but if they chose not to, the EPA would implement the CEIP in those states. Thus, we invite comment on the CEIP provisions we are proposing as optional example CEIP regulatory text, including to the extent that text may be applied by the EPA through a federal plan.

This action is undertaken pursuant to the authority in section 111(d) of the CAA, as well as the Agency's general rulemaking authority as necessary to carry out the functions of the CAA, 42 U.S.C. 7411(d), 7601(a). This rulemaking action is subject to the rulemaking provisions of the CAA set forth in section 307(d), 42 U.S.C. 7607(d). This action is nationally applicable because it would establish additional requirements for states that choose to opt into the CEIP.

The EPA's action in this proposal is consistent with, and the EPA's authority to proceed with this action is unaffected by, the Supreme Court's orders in *West Virginia, et al.* v. *EPA, et al.,* No. 15A773 (February 9, 2016). The Court granted applications for a stay of the Clean Power Plan EGs pending disposition of the Stay Applicants' petitions for review of the EGs in the U.S. Court of Appeals for the District of Columbia Circuit, including any subsequent review by the Supreme Court. That litigation is currently pending, and the Supreme Court's stay is in effect.

A stay has the effect of "halting or postponing some portion of [a] proceeding, or [ ] temporarily divesting an order of enforceability." *Nken* v. *Holder,* 556 U.S. 418, 428 (2009). A stay is distinct from an injunction, which "direct[s] the conduct of a particular actor." *Id.*

The EPA has not been enjoined by any court from continuing to work with state partners in the development of frameworks to reduce CO_2 emissions from affected EGUs.

This action proposes several changes and additions to the CEIP, which is an optional program, and proposes optional example regulatory text for use by states in the design of their plans. This is wholly consistent with the EPA's statutory authorities and the precedents discussed later in this preamble, and is consistent with and unaffected by the February 9, 2016 stay orders. A state may participate in the CEIP only after the EPA approves a required state plan or the EPA promulgates a federal plan for that state that includes the CEIP. These actions will not occur until sometime after the judicial stay has been lifted. Thus, this action is consistent with, and the EPA's authority to proceed with this action is unaffected by, the stay.

Furthermore, we note that in addition to its CAA section 111 and CAA section 301 authority to engage in this rulemaking, the EPA possesses multiple other authorities under the CAA that direct it to engage in capacity building and provide technical and financial assistance to states in order to effectuate the air pollution reduction objectives of the CAA.[12] These authorities typically support, but operate independently of, the CAA's regulatory mandates. Under section 102 of the CAA, for example, the EPA shall "encourage cooperative activities by the States and local governments for the prevention and control of air pollution; encourage the enactment of improved and . . . uniform State and local laws relating to the prevention and control of air pollution; and encourage the making of agreements and compacts between States for the prevention and control of air pollution." 42 U.S.C. 7402(a). The EPA is also authorized under section 103 of the CAA to conduct a variety of research and development activities, render technical services, provide financial assistance to air pollution control agencies and other entities, and conduct and promote coordination of training for individuals—all for the purpose of the "prevention and control of air pollution." 42 U.S.C. 7403(a).

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[10] See 40 CFR 60.5737.

[11] The EPA intends for the CEIP to be considered severable from the remainder of the Clean Power Plan. As an optional program that is not required for achievability of the emission performance rates or equivalent state goals, the CEIP is in fact severable. Although the Agency believes, as explained in the preamble to the final EGs, that the CEIP provides a number of benefits, 80 FR 64829–64831, nonetheless, all other aspects of the Clean Power Plan would still be implementable in the absence of the CEIP.

[12] It is undisputed that CO_2, as a greenhouse gas, is an air pollutant under the CAA. *See Massachusetts* v. *EPA,* 549 U.S. 497, 528–532 (2007).

The EPA may, among other things, "collect and disseminate, in cooperation with other Federal departments and agencies, and with other public and private agencies, institutions, and organizations having related responsibilities . . . information pertaining to air pollution and the prevention and control thereof." *Id.* § 7403(b). The CAA expressly authorizes the Agency to develop "nonregulatory strategies . . . for preventing or reducing multiple air pollutants, including . . . carbon dioxide, from stationary sources, including fossil fuel power plants." *Id.* § 7403(g).

Taken together, these provisions both establish that the EPA has the authority, and illustrate why the EPA would have good reason, to continue coordinating and assisting in the development of CO_2 pollution prevention and control efforts of the states and local governments, even in light of the stay of the Clean Power Plan.

The EPA has proceeded under a similar understanding of its authority when CAA rules have been judicially stayed pending review in the past. When the D.C. Circuit Court stayed the Cross-State Air Pollution Rule (CSAPR), *EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302 (D.C. Cir. December 30, 2011), the EPA proceeded to issue two rules making a number of revisions to the stayed rule. The EPA noted that its actions in revising the rule were "consistent with and unaffected by the Court's Order staying the final [CSAPR]. Finalizing this action in and of itself does not impose any requirements on regulated units or states." 77 FR 10324, 10326 (February 21, 2012). Indeed, one of the changes the EPA undertook while the stay was in effect was a delay of the effective date of certain "assurance provisions" "in order to neutralize a key uncertainty facing successful and potentially rapid program implementation following the current stay, such that sources can rely on *immediate activation* of a [CSAPR] allowance market." *Id.* at 10331 (emphasis added). In another set of revisions finalized in June of 2012, the EPA again took action making a number of important changes, including state budget adjustments and revision of set-aside accounts for new sources, while the stay of the rule was in effect. *See* 77 FR 34830 (June 12, 2012). Among other things, the EPA rejected a comment to revise the set-aside accounts for years for which the EPA had already recorded allowances in compliance accounts prior to the stay being issued. *Id.* at 34838–34839. The EPA explained that because the allowances were already recorded, they were freely available to their owners to be transferred or sold and may no longer be in the original owners' accounts. The Agency rejected the commenter's expansive interpretation that the judicial stay meant "these allocations are no longer distributed for use." *Id.* Rather, in the EPA's view, the stay meant that "sources are not required to hold allowances for compliance at this time," but that did not mean the allowances themselves did not remain in circulation. *Id.*

Similarly, when the D.C. Circuit Court stayed the nitrogen oxide (NO_X) state implementation (SIP) Call, issued under authority of CAA section 110(k)(5), *Michigan* v. *EPA,* No. 98–1497 (D.C. Cir. May 25, 1999), the Agency proceeded to institute direct federal regulation of the sources to achieve functionally the same result under CAA section 126(c). *See* Findings of Significant Contribution and Rulemaking on CAA section 126 Petitions for Purposes of Reducing Interstate Ozone Transport, 65 FR 2674, 2680 (January 18, 2000). In reviewing and upholding the EPA's direct federal regulation under CAA section 126, the D.C. Circuit Court addressed the issue of whether the EPA could proceed under CAA section 126 in light of the stayed NO_X SIP Call under CAA section 110. Noting that the "congruence" between the EPA's schedules for action under the separate provisions had been disrupted by its stay order, and that the conditions under which the EPA had originally deferred action under CAA section 126 were no longer present, the Court upheld the Agency's authority to proceed under CAA section 126 and deferred to the Agency's interpretation that the two provisions "operate independently" such that proceeding with regulation under CAA section 126 was not unlawful. *Appalachian Power Co. et al.* v. *EPA,* 249 F.3d 1032, 1045–48 (D.C. Cir. 2000). To be clear, the EPA is not proposing to institute direct regulation of the affected EGUs in this action nor is the Agency proposing to implement the CEIP while the stay is in effect. Rather, the court's analysis in *Appalachian Power* supports the Agency's view that a stay does not affect its ability to conduct activities that are not in themselves dependent for their authority on the effectiveness of the stayed action.[13]

While none of the Clean Power Plan's deadlines can be enforced while the stay remains in effect, at this point it is not clear whether and to what extent those deadlines will necessarily be tolled once the stay is lifted. Some of the stay applicants expressly requested that all of the Clean Power Plan's deadlines be tolled for the period between the Clean Power Plan's publication and the final disposition of their lawsuits. *See, e.g.,* Appl. of Util. & Allied Parties for Immediate Stay of Final Agency Action Pending Appellate Review 22. In its brief, the government interpreted that form of relief to be requested (either explicitly or implicitly) by all of the applicants, and it opposed the stay in part on the grounds that such relief would be "extraordinary and unprecedented." Mem. for Fed. Resps. in Opp. 3; *see id.* 70–71. In their reply brief, the 29 State Applicants clarified that they were only seeking a "straightforward" Administrative Procedure Act stay that would merely "temporarily divest[ ] [the Clean Power Plan] of enforceability," such that "the States need not comply with any of the [Clean Power Plan's] deadlines *that will occur during this litigation.*" Reply of 29 States and State Agencies in Support of Appl. for Immediate Stay 29 (emphasis added). The States disagreed that granting the stay would necessarily require day-for-day tolling of every Clean Power Plan deadline for the period between the Clean Power Plan's publication and the conclusion of the lawsuit. *Id.* at 30. They stated that although such tolling "would be appropriate as a matter of basic fairness," "the exact shape of such an equitable disposition *need not be decided today.*" *Id.* at 30 (emphasis added) (citing *Michigan* v. *EPA,* no. 98–1497, Dkt. 524995 (D.C. Cir. 1999), for an example of a case in which the Court of appeals decided whether and how to toll relevant deadlines *after* the challenged rule was upheld). The Supreme Court's orders granting the stay did not discuss the parties' differing views of whether and how the stay would affect the Clean Power Plan's deadlines, and did not expressly resolve that issue. In this context, the legal effect of the stay on the Clean Power Plan's deadlines is ambiguous, and the question of whether and to what extent tolling is appropriate will need to be resolved once the validity of the Clean Power Plan is finally adjudicated. At that point, the effect of the stay will be able to be assessed in light of all relevant circumstances.

Because it is currently unclear what adjustments, if any, will need to be made to implementation timing, the EPA is in general in this action maintaining the timing elements of the

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[13] *See also Air Transp. Ass'n of Am.* v. *U.S. Dep't of Transp. et al.,* 613 F.3d 206, 209 (D.C. Cir. 2010) (upholding Federal Aviation Administration's institution of airport congestion pricing while "slot auctions" regulation to solve the same congestion problem was judicially stayed pending review).

CEIP that have already been finalized, recognizing that they may need to be adjusted in concert with other timing elements of the Clean Power Plan. In particular, we continue to refer to the period during which generation and savings may be eligible to earn early action allowances or ERCs as 2020 and 2021. We propose to retain the start date for project eligibility as September 6, 2018, for demand-side EE projects implemented in low-income communities, but are proposing a start date of January 1, 2020, for eligible CEIP RE projects, including those implemented in low-income communities. However, we propose to remove the alternative earlier date related to the date of final state plan submittal. These proposed changes are discussed in section III.C of this preamble. The decision not to propose further changes to the key timing elements of the CEIP in this action should not be taken to indicate any particular view or intention by the Agency regarding how the timelines for the Clean Power Plan overall may be impacted by the Supreme Court's stay.

C. How does this action relate to the final Clean Power Plan and proposed federal plan and model trading rules?

As noted previously, the EPA took final action in the Clean Power Plan to establish the CEIP, and finalized certain aspects of the CEIP at 40 CFR 60.5737, while identifying other details that it would address in a future action. *See* 80 FR 64829–64832, 64943. In the proposed federal plan and model trading rules for the Clean Power Plan, the EPA requested comment on a number of details for the CEIP that had been identified in the final EGs, and also proposed provisions to implement the CEIP under the federal plan and model trading rules. *See* 80 FR 65025–65026. In this action, we are proposing the design details we identified as needing to be addressed. We are also proposing several adjustments to the CEIP as finalized in the Clean Power Plan EGs, reflecting new information and feedback from stakeholders after the EGs were finalized. This action does not re-open those aspects of the CEIP as finalized that the EPA is not expressly proposing to change or requesting comment on. We are also re-proposing the CEIP-related aspects of the mass-based and rate-based model trading rules, which we characterize in this proposal as optional example regulatory text.[14] We are not re-proposing federal plan CEIP provisions, but request comment on the limited issue of the suitability of these more detailed, re-proposed optional example CEIP provisions for possible use in a federal plan.[15]

In the proposed federal plan and model trading rules for the Clean Power Plan, the EPA expressed its intent to implement the CEIP in states that may become subject to a federal plan; *see* 80 FR 64978 (October 23, 2015). The Agency proposed a mass-based and a rate-based approach to implementing the CEIP as part of the federal plan.[16] *See* 80 FR 65066–65067 (proposing a CEIP set-aside as part of a mass-based plan at 40 CFR 62.16235(e)); *id.* at 65092–65093 (proposing a rate-based CEIP program at 40 CFR 62.16431). As was generally the case for the federal plan and model trading rules, these proposed federal plan provisions also served as proposed model rule provisions that would be presumptively approvable if adopted in state plans. *See generally* 80 FR 64973.

The EPA has determined to remove these CEIP provisions from the larger model trading rules rulemaking, and to re-propose optional example regulatory text for the CEIP as part of this proposal. With regard to the proposed federal plans, the EPA is not re-proposing CEIP federal plan provisions in this action, but invites comment on the presumptively approvable example approach, including to the extent it provides additional detail on the approach that EPA could take in a federal plan. As proposed in this action, this example text provides greater specificity than the October 23, 2015 proposal on the requirements that may be included in any potential future federal plan CEIP.[17] The Agency believes it is administratively simpler and more convenient for the public to be able to review and comment on any optional example regulatory text related to the CEIP in conjunction with all of the other CEIP design details being proposed in this action. Thus, this action constitutes, in part, a re-proposal of optional example CEIP provisions, replacing and superseding the proposed CEIP provisions that were included in the model trading rules published in the **Federal Register** on October 23, 2015. The EPA invites comments on this re-proposed optional example regulatory text as an approach states or the EPA could take in state or federal plans, respectively.

In some instances, those proposed provisions are being re-proposed without significant changes; in others, proposed CEIP revisions to the EGs presented in this action necessitated corresponding changes to the mass- and rate-based optional example regulatory text. However, the October 2015 proposal did not contain specific proposals for certain design details that are now being proposed here. The EPA intends to finalize the CEIP optional example rule text included in this action in conjunction with the finalization of the other CEIP design details proposed in this action. We do not intend to include the CEIP optional example rule text as part of the finalized model trading rules. Nonetheless, the finalized CEIP optional example rule provisions could be integrated with the finalized mass-based or rate-based model trading rules when EPA finalizes this CEIP rulemaking, where a state chooses to implement the CEIP. Thus, the CEIP optional example rule text is being proposed in the same subpart of the Code of Federal Regulations as the full model trading rules, in order to facilitate states wishing to adopt a model rule that includes the CEIP.

Since the CEIP is an optional program, should the Agency not be able to approve a state's CEIP, the Agency believes that the provisions would be severable and not impact the Agency's ability to approve the remainder of a state's final plan submission. In addition, because the CEIP is an optional program, the Agency does not anticipate that it would promulgate a partial federal plan addressing the CEIP in the circumstance where a state plan is approvable but its CEIP provisions are not. However, consistent with what we stated in the October 2015 federal plan and model trading rules proposal, the EPA continues to intend to implement the CEIP if it were to promulgate a full federal plan for a particular state, *see* 80 FR 64978.

In addition, in the event that the EPA promulgates CEIP provisions as part of a federal plan for a particular state, the state may subsequently be able to take over the implementation of the CEIP through one of two separate mechanisms. The state may either take a delegation of the federal plan (or a partial delegation covering just the CEIP), or the state may submit a partial state plan for implementation of the CEIP upon EPA's approval.

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[14] We are not re-proposing any aspects of the model rules that are un-related to the CEIP.

[15] In the fall of 2015, during the federal plan and model trading rules proposal comment period, the EPA, through informal outreach efforts, received feedback from stakeholders that a separate regulatory action on the design details of the CEIP was appropriate.

[16] For the purposes of a rate-based federal plan, the EPA notes that as currently proposed, demand-side energy-efficiency measures may only be awarded ERCs in the context of the CEIP.

[17] The EPA does not intend to finalize any provisions related to implementation of the CEIP as part of a federal plan until the actual promulgation of a federal plan, which would not occur until lifting of the stay and an EPA determination of a subsequent failure of a state to timely submit a plan or EPA disapproval of a state plan.

The general process for delegation of federal plans under section 111(d) was explained in the October 2015 proposal, *see* 80 FR 65032–33. The EPA is not proposing any changes to this existing process, and we recognize the ability of states with a federal plan in place to take a delegation of the CEIP, similar to other section 111 federal regulations. A delegation of the CEIP would generally mean that a state with adequate resources and legal authority would operate the CEIP, subject to the EPA's oversight and except for any functions that the EPA may retain for itself upon delegation. Eligible project providers would come to the state agency with the delegated EPA authority in order to present applications and submittals under the CEIP, and the state would review these applications and submittals and issue early action ERCs or allocate early action allowances. In delegating the CEIP, the EPA would follow its existing New Source Performance Standards (NSPS) delegations guidance and the EPA Delegations Manual, Delegation 7–139, "Implementation and Enforcement of 111(d)(2) and 111(d)(2)/129(b)(3) federal plans," which, among other things, call for the state to enter into a memorandum of agreement with the relevant EPA Regional Administrator, in order to take delegation of the program. *See* 80 FR 65032–33.

States may also be in a position to take over direct implementation of the CEIP in their own right through a partial state plan. As we proposed in the October 2015 federal plan and model trading rules proposal, the EPA may approve partial state plans to implement a portion of the EGs under section 111(d). The EPA specifically recognized that certain aspects of the Clean Power Plan implementation may be appropriate for states to handle through a partial state plan, for instance, decisions as to the method of allocation of allowances under a mass-based federal plan. *See id.* at 65027–65029. We believe the CEIP is similarly a program under the Clean Power Plan that could be appropriately submitted and administered by a state operating under an otherwise-federal plan. Unlike a delegation, a partial state plan requires a submission process for EPA approval as for a full state plan, including a demonstration of adequate legal authority and that procedural requirements, such as public notice and opportunity to comment on the partial state plan, are satisfied.

Finally, we note that in the October 23, 2015, model trading rules and federal plan proposal the EPA requested comment on a number of details regarding CEIP program design that were not limited to the federal plan and model trading rules, but pertained to general design parameters or details not addressed in the final EGs. *See* 80 FR 65025–65026. These topics related to CEIP requirements that would be applicable to all states opting to participate in the program (*i.e.,* these issues would not be limited to model trading rules or federal plans). The bulk of this proposal is dedicated to addressing these topics through a set of additional provisions in the EGs at 40 CFR 60.5737.

The EPA values the comments related to the topics that have been submitted to date, both on the October 23, 2015, proposal as well as to the CEIP non-regulatory docket that closed on December 15, 2015. We have reviewed and considered the comments submitted through the federal plan and model trading rules rulemaking docket that closed on January 21, 2016, as well as the non-regulatory docket. These comments have informed various aspects of this proposal. We encourage those who have submitted comments already on the CEIP to re-submit those comments and/or any updated or additional comments through the comment submittal process for this rulemaking proposal. We heard from many stakeholders that they would like an opportunity to comment on a more developed proposal regarding these CEIP topics; the EPA is responding to those requests by issuing this proposal, which provides a new opportunity to submit comments on the CEIP topics addressed here. In order to ensure that the EPA considers and responds to your comments on these CEIP topics, you must submit your comments on this proposal, following the process explained in the section titled **ADDRESSES**.

D. What key comments were received during the informal feedback process?

In an effort to obtain stakeholder feedback on the CEIP, the EPA engaged in broad outreach activities. Approximately 750 stakeholders (potential project providers, environmental justice (EJ) groups, community groups, state and local governments, tribes and environmental non-governmental organizations) participated in at least one of four listening sessions on the CEIP. These listening sessions were part of an overall outreach effort that also included two workshops focused on community concerns, dozens of stakeholder meetings, conference appearances and one-on-one discussions since August 2015 that helped to inform this proposal.

Additionally, the EPA opened a non-regulatory docket (EPA–HQ–OAR–2015–0734) requesting pre-proposal input on the design details of the CEIP covered in this package. Specifically, the EPA requested input on the following: (1) What the EPA should consider when defining criteria, terms and requirements under the CEIP; (2) what the EPA should consider regarding the timing and distribution of EPA matching allowances or ERCs under the CEIP; and (3) what the EPA should consider when designing the mechanics of the CEIP. The non-regulatory docket received more than 5,000 comments.

While not within the scope of our requests, many commenters supported the inclusion of the CEIP in the Clean Power Plan. These commenters stated, however, that the CEIP project eligibility start date tied to submission of a final state plan, and the limitation of CEIP matching awards for eligible energy savings or generation to the years 2020 and 2021 only, were too restrictive. With regard to the project eligibility start date, commenters asserted that RE and EE projects take time to design, implement and begin generating/saving MWh, especially those that are developed with, by, and for low-income households and communities. Again, while not all of these topics are within the scope of this action, in response to some of these concerns, the EPA is proposing a modification to make clear when eligibility may begin for projects, as discussed further in section III.C of this preamble.

With regard to apportionment of the EPA matching pool of allowances and ERCs among the states, the majority of commenters felt that the pro-rata distribution method identified in the final Clean Power Plan EGs, whereby each state's share is based on the amount of reductions from 2012 levels the affected EGUs in the state are required to achieve relative to those in the other CEIP-participating states (80 FR 64830; October 23, 2015), was the appropriate apportionment method. Some commenters suggested that, rather than apportioning the matching pool among the states, the pool should instead be available on a first-come, first served basis to eligible CEIP project developers, regardless of where such projects take place. The EPA agrees with the majority of commenters that supported a state-by-state apportionment, as the Agency believes this is consistent with the state plan structure of the Clean Power Plan, and it ensures that all states that choose to participate in the CEIP have access to the additional allowances and ERCs supplied by the matching pool. Therefore, the EPA is proposing in this action the size of the matching pool for each state, in line with the pro-rata distribution methodology previously described (*see tables 1 and 2* in section III.A of this preamble). The EPA has provided the calculations supporting these numbers in a technical support document (TSD) in the docket for this proposal.[18]

Some commenters stated that the EPA matching pool of 300 million short tons of CO_2 should be divided evenly into two reserves: one reserve for wind and solar projects, and another reserve for low-income EE projects. Others supported a different division, largely commenting that a greater share of the matching pool should be reserved for low-income EE projects. There was also strong support for allowing flexibility for states to decide the size of the two reserves. The EPA has considered those comments and proposes that the matching pool should be divided evenly into two reserves, but seeks comment on several other approaches for distributing the pool as discussed further in section III.A.

With regard to the definition of low-income community, many commenters suggested each state should have flexibility to choose the definition(s) that may be employed by project providers seeking early action awards from the state. Commenters supported the use of definitions of low-income currently used by other federal incentive programs, such as 80 percent of the area median income,[19] Department of Housing and Urban Development (HUD) criteria,[20] Empowerment Zones criteria,[21] or an annual income at or below 200 percent of the federal poverty level.[22] However, other commenters suggested that states should not be allowed this flexibility, and rather that the EPA should provide a definition that all states must use. Many of the definitions referenced by commenters address "low-income" at the individual household level. By contrast, some commenters stated that a geographically based definition (*i.e.*, Census tract- or neighborhood-level, or zip codes with above-average concentrations of low-income individuals) is most appropriate, and allows for the most comprehensive approach to program delivery; other commenters stated CEIP plans should not geographically restrict or allow the exclusion of low-income households within a state, as such an exclusion would create a disparate impact and unduly harm low-income households. Some commenters stated that a hybrid approach that would include both geographically based definitions as well as household level definitions would be most appropriate to ensure that low-income communities, as well as low-income residents that are not within low-income communities are both eligible to receive CEIP matching awards for EE projects. A few commenters stated that the double-match for energy-efficiency projects should be extended beyond low-income communities, and also be made available for minority populations and in Indian Country. The EPA further discusses the definition of "low-income," for purposes of implementing the CEIP in section III.B.

With regard to the criteria for eligible EE projects in low-income communities, commenters suggested that eligibility go beyond single family residential projects and that states should consider additional factors such as economic development and job creation when prioritizing EE and RE projects. Requirements for CEIP-eligible projects are discussed in section III.C of this preamble.

Although the EPA did not request comment on the types of RE projects that should be eligible for consideration, several commenters requested that, in addition to wind and solar resources, the EPA consider including geothermal, biomass and hydropower, as well as other generating technologies such as combined heat and power (CHP) and waste heat to power (WHP). One commenter requested that nuclear generation be considered as an eligible RE technology, however, several other commenters explicitly stated that the EPA should not consider nuclear as an eligible RE technology. The Agency also received several petitions for reconsideration on the final Clean Power Plan requesting that the scope of CEIP eligibility be expanded.[23] In this action, we are proposing a limited expansion of the list of CEIP-eligible RE technologies beyond wind and solar, to two other renewable, zero-emitting technologies: Geothermal and hydropower (We note these technologies were also considered in the formulation of building block 3 of the BSER. *See* 80 FR 64807, October 23, 2015). Commenters also suggested expanding eligibility of low-income projects to include certain RE technologies, such as solar, that could benefit low-income communities in the same way that energy efficiency projects can. We agree that low-income communities can benefit from additional incentives for solar resources, similar to the benefits that would be realized for EE. We also recognize that deployment of RE projects in low-income communities face barriers similar to those faced by low-income EE projects. Accordingly, we are proposing that solar projects implemented to serve low-income communities that provide direct electricity bill benefits to low-income community ratepayers would be eligible for CEIP awards from the low-income community reserve, and that such projects would be eligible for the same (two-for-one) CEIP incentive available to low-income EE projects. Discussions on these proposed provisions are located in sections III.C.4 and III.C.5 of this preamble.

Commenters requested that the EPA provide early guidance on a methodology for representing the 300 million short tons of CO_2 EPA matching pool in the form of ERCs, which are denominated in MWh. Such guidance is provided in section III.A of this preamble. Commenters also supported flexibility for states to identify the mechanism used for tracking MWh generated or avoided by eligible CEIP projects.

The majority of commenters asserted that EM&V requirements used to quantify CEIP-eligible MWh generated or saved should be flexible and transparent, should not be overly burdensome (*i.e.*, the cost of the EM&V should be balanced with the accuracy and reliability of the results), should not present a significant disincentive to participation in the CEIP, and that states that already have robust quantification and verification processes in place should be allowed to rely on these processes. Additionally, there was some support for independent verification of the EM&V methods, procedures, and assumptions used to quantify MWh for eligible CEIP projects (*i.e.*, independent verification of EM&V plans as well as subsequent M&V reports). These commenters suggested that the EPA should be responsible for developing and maintaining a list of approved independent verifiers, and some suggested that EPA should provide template EM&V plans and M&V reports. Section III.B discusses state plan requirements for distribution of early action allowances or ERCs, including considerations for EM&V of CEIP-eligible MWh.

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[18] See TSD titled "Apportionment of the Matching Pool among the States".

[19] HUD.GOV, FY 2015 Income Limits, *https://www.huduser.gov/portal/datasets/il/il15/index.html*.

[20] *et seq.*

[21] Programs of HUD, *http://portalhud.gov/hudportal/HUD%3Fsrc%3D/hudprograms/empowerment_zones*.

[22] Federal Poverty Guidelines, February 2015, *http://familiesusa.org/product/federal-poverty-guidelines*.

[23] While there is some overlap in this action on this and several other issues relating to the CEIP raised by the petitions for reconsideration, the Agency continues to review, and is not acting on, these or any other aspects of the petitions for reconsideration of the Clean Power Plan at this time.

The EPA also received comments on what, if any, reapportionment process should take place for EPA matching allowances or ERCs that a state is eligible to receive, but that the state does not ultimately access because it chooses not to opt in to the CEIP, or the CEIP provisions of its otherwise approved state plan are disapproved by the EPA. Commenters were nearly evenly divided on whether these "extra" matching allowances or ERCs should be reapportioned to CEIP-participating states on a pro-rata basis, or whether they should be made available to CEIP-participating states on a first-come, first-served basis, based on state awards of early action allowances or ERCs to eligible CEIP projects. Other commenters stated that EPA matching allowances or ERCs that are apportioned to a state, but ultimately are not used by that state because it chooses not to opt in to the CEIP, should not be reapportioned among CEIP-participating states. Based on some stakeholder concerns and further consideration by the Agency, the EPA is not including provisions for reapportionment among states in this proposal. See section III.A of this preamble for a discussion on the reasons for excluding reapportionment provisions for any remaining CEIP credits, and a request for comment on whether reapportionment should be included in the CEIP.

Many commenters supported broad geographic eligibility for participation in the CEIP, including supporting the inclusion of projects located in states, tribal lands and territories without affected EGUs, or for whom the EPA has not yet established goals under the Clean Power Plan EGs. Please see section III.D for a discussion on CEIP participation for states, tribes and territories for which the EPA has not established goals.

III. Clean Energy Incentive Program Design Details

In this section, we discuss the proposed design details for several elements of the CEIP. Section III.A presents the proposed provisions for matching allowances and ERCs to be issued by the EPA from the matching pool of 300 million short tons of CO_2 emissions. This includes a discussion of how EPA proposes to translate the pool into matching allowances and matching ERCs; the number of allowances or ERCs that may be allocated or issued by a state to a CEIP-eligible project provider per MWh generated or saved; the division of the EPA matching pool into a reserve for RE projects and a reserve for low-income community projects; the apportionment of the EPA matching pool among the states; and whether to include reapportioning EPA matching allowances and ERCs among CEIP-participating states.

Section III.B of this preamble discusses requirements for states that choose to participate in the CEIP. It includes requirements for allocation of early action allowances or issuance of early action ERCs by a state; requirements for a proposed process by which EPA matching allowances or matching ERCs would be awarded; options for meeting the requirement finalized in the Clean Power Plan EGs to maintain the stringency of mass-based or rate-based CO_2 emission performance by affected EGUs when implementing the CEIP; the requirement for a state to select one or more existing definitions of "low-income community" for purposes of implementing the CEIP; and requirements addressing the potential improper allocation or issuance of early action allowances or early action ERCs by a state.

Section III.C of this preamble discusses requirements for CEIP-eligible projects, including eligible RE projects and eligible low-income community projects. This includes a proposal to clarify the term "project" to also include programs that deploy eligible RE technologies and implement demand-side EE. It also includes a proposal to clarify the definition of "commence construction" as applied to RE projects, as well as a discussion of the option for a state to use an Agent for reviewing CEIP project applications, allocating early action allowances, and issuing early action ERCs. In addition, this section proposes the expansion of eligible CEIP RE projects to include, in addition to wind and solar, two other RE technologies: Geothermal and hydropower. The section also proposes an expansion of technologies implemented in low-income communities that would be eligible to receive a two-for-one CEIP award. Specifically, we propose that solar projects implemented to serve low-income communities that provide direct electricity bill benefits to low-income community ratepayers also be eligible for a two-for-one award in addition to the demand-side EE technologies that are already included. For this reason, we now refer to this reserve as the 'low-income community' reserve instead of the former 'demand-side EE' reserve. Finally, this section proposes that states have flexibility to determine the types of demand-side EE projects they may deem eligible for CEIP awards (such as projects for residences and non-profit commercial buildings, or transmission and distribution projects that reduce electricity use on the customer side of the meter), so long as they are implemented in communities that meet the state's approved definition(s) for "low-income community."

Section III.D of this preamble discusses CEIP participation for states, tribes and territories for which the EPA has not established goals in the Clean Power Plan EGs. This includes a proposal that may further enhance the ability of project providers located in Indian country without affected EGUs to participate in the CEIP, a request for comment on how to determine the appropriate portion of the matching pool that should be apportioned to the non-contiguous states and territories, if they choose to participate in the CEIP, and a discussion of how eligible CEIP projects developed in states without affected EGUs may receive early action allowances or ERCs from another state that has chosen to participate in the CEIP.

A. Provisions for Matching Allowances and ERCs To be Issued by the EPA From the 300 Million Short Ton Pool

As discussed in section II.A of this preamble, the EPA established an overall matching pool of 300 million short tons of CO_2 to be made available for states participating in the CEIP. Participating states that allocate early action allowances or issue early action ERCs are able to receive matching allowances or matching ERCs from the EPA from this matching pool. In this action, we are proposing a methodology to determine a state's pro rata share of the matching pool for both mass- and rate-based programs. The EPA is proposing to use this methodology to determine the amount of matching allowances or ERCs that will be available to each CEIP-participating state. We are also proposing that a state may only allocate or issue early action allowances or ERCs to eligible CEIP projects in a total amount not to exceed the number of matching ERCs or allowances that are apportioned to the state.[24]

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[24] The EPA notes that, while a mass-based state may not allocate from its CEIP early action set-aside a number of allowances larger than the number of matching allowances available to the state, such a state could choose to create an additional allowance

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Additionally, this action proposes a division of the matching pool that would establish the portion of the matching pool available to each CEIP-participating state for awards to eligible CEIP RE projects, and the portion of the matching pool available to each CEIP-participating state for awards to eligible CEIP low-income community projects.

1. The Size of the EPA Matching Pool in Terms of Allowances and ERCs

As stated in the preamble of the final Clean Power Plan, the EPA determined that the matching pool of 300 million short tons of CO_2 emissions was an appropriate reflection of the CO_2 emission reductions that could be achieved in 2020 and 2021 through additional early investment in technologies with zero associated CO_2 emissions, 80 FR 64830. We recite this information as it is relevant to our calculation of the size of the pool in terms of allowances and ERCs, but we are not reopening the size of the matching pool as finalized in the EGs. To estimate short tons of CO_2, the EPA projected that potential additional early investment in wind and solar could result in 400 million MWh of clean generation in 2020 and 2021, and applied the assumption that each MWh displaces approximately 0.8 short tons of CO_2 from carbon-emitting generation per MWh of clean energy generation.[25] 400 million MWh multiplied by 0.8 short tons of CO_2 per MWh results in 320 million tons. The EPA applied a conservative downward adjustment to this calculation to set the size of the matching pool at 300 million short tons.

The EPA is using the relationship between tons of CO_2 and allowances that was established in the final Clean Power Plan EGs in order to determine the overall amount of matching allowances available through the EPA matching pool. Under a mass-based state plan, an allowance represents a limited authorization to emit one ton of CO_2. The matching pool was established in the EGs at 300 million short tons of CO_2, which would be equivalent to 300 million allowances. Thus, the EPA matching pool, in the form of allowances, will be equal to 300 million allowances.

The EPA is using the relationship between MWh and ERCs that was established in the final Clean Power Plan EGs, along with an adjustment identical to that applied when setting the matching pool at 300 million short tons, in order to determine the overall number of matching ERCs available through the EPA matching pool. Under a rate-based state plan, each MWh of generation or savings from an eligible resource that meets all applicable requirements of the EGs may be issued one ERC by a state. The EPA is proposing to establish the size of the matching pool, in the form of ERCs, based on the projection of 400 million MWh of wind and solar generation in 2020 and 2021, with the application of the same conservative downward adjustment the EPA used to adjust 320 million short tons of CO_2 emissions downward to 300 million short tons in setting the size of the matching pool in the final Clean Power Plan. As follows, the EPA proposes that the size of the matching pool, in the form of ERCs, will be equal to 375 million ERCs.

The establishment of the matching pool in terms of both allowances and ERCs does not have any bearing on the final Clean Power Plan's provisions that allowances from a mass-based emission budget trading program may not be used for compliance in a rate-based emission trading program and that ERCs may not be used for compliance in a mass-based emission budget trading program. Allowances and ERCs are distinct tradable compliance instruments used by states implementing mass-based and rate-based emission standards, respectively, and are not interchangeable under the Clean Power Plan EGs, *see* 40 CFR 60.5750(d); *id.* 60.5790(a); 80 FR 64839. Using a single multiplication factor on a one-time basis to represent the matching pool in both forms—allowances and ERCs—is done simply for the limited purpose of providing for the implementation of the CEIP in the context of either a mass-based or a rate-based emission trading program.

2. Awards for CEIP-eligible MWh, in Terms of ERCs and Allowances

The final Clean Power Plan EGs specified the ERC award ratios (both by a state and the EPA) for MWh of generation or energy savings achieved by an eligible project under the CEIP.[26] These award ratios would be applied by a state with a rate-based state plan that chooses to implement the CEIP. Specifically, eligible CEIP RE projects may receive an award of two ERCs for every two MWh of clean energy generated. This award is based on the issuance of one early action ERC by the state and the award of one matching ERC by the EPA. In addition, eligible low-income community projects are eligible for a "double" award of four ERCs for every two MWh of energy savings. This award is based on the issuance of two early action ERCs by the state and the award of two matching ERCs by the EPA.

For example, if a CEIP-eligible RE project generates 50 MWh in 2020, the project would be eligible to receive 25 early action ERCs from the state and 25 matching ERCs from the EPA, for a total award of 50 ERCs. As another example, if a CEIP-eligible low-income community project saves 50 MWh in 2020, the project would be eligible to receive 50 early action ERCs from the state and 50 matching ERCs from the EPA, for a total award of 100 ERCs.

While the final Clean Power Plan EGs specified the ERC award ratios for CEIP-eligible MWh that may be used by rate-based states, we stated that the Agency would propose in a future action the allowance award ratios for CEIP-eligible MWh that mass-based states may use. As follows, in this action the EPA is proposing that the allocation of early action allowances by a state, and the award of matching allowances by the EPA, will be based on a 0.8 short tons of CO_2/MWh factor. As discussed previously in this section, this is the same factor applied by the EPA when it established the size of the matching pool of 300 million short tons of CO_2 emissions (see 80 FR 64830).

For eligible CEIP RE projects under a mass-based program, the proposed 0.8 short tons of CO_2/MWh factor would result in a total of 0.8 allowances awarded for every one MWh. Again, with half of the total award being made by the state in the form of allocated early action allowances, and the other half of the award being made by the EPA in the form of matching allowances, both the state and EPA would provide 0.4 allowances for each MWh generated, for a total of 0.8 allowances.[27] For example, if a CEIP-eligible wind project generates 50 MWh in 2020, the total potential combined award available from the state and the EPA would be 40 allowances (*i.e.*, 50 MWh × 0.8 short tons CO_2/MWh). The project would be eligible to receive an allocation of 20 early action allowances from the state and award of 20 matching

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set-aside from which it could allocate allowances to incentivize additional early investments in RE or EE. In general, a state has full discretion to allocate its allowances as it sees fit.

[25] 0.8 short tons of CO_2 per MWh is approximately the CO_2 emission intensity of all affected sources in 2012. See Data File: Goal Computation Appendix 1–5, TSD to the Clean Power Plan Final Rule titled Emission Performance Rate and Goal Computation.

[26] These provisions are discussed in section VIII.B.2 of the preamble to the final EGs (80 FR 64830, October 23, 2015). See also 40 CFR 60.5737(b) of the EGs.

[27] Allowances may only be allocated or awarded in whole-allowance increments.

allowances from the EPA, for a total award of 40 allowances.

Given the two-to-one award available to low-income community projects, for each MWh of CEIP-eligible energy savings or generation from a low-income community project under a mass-based program, a CEIP project provider would be eligible to receive 0.8 early action allowances from the state and 0.8 matching allowances from the EPA, for a total award of 1.6 allowances per MWh. For example, if a CEIP-eligible low-income community project saves 50 MWh in 2020, the total combined award available to the project would be 80 allowances (*i.e.*, 50 × 0.8 short tons CO_2/MWh × 2 (to account for the two-to-one award ratio, per MWh of energy savings)). The project would be eligible to receive an allocation of 40 early action allowances from the state and an award of 40 matching allowances from the EPA, for a total award of 80 allowances.

3. Division of the Matching Pool of 300 Million Short Tons of CO_2 Emissions Into a Reserve for RE Projects and a Reserve for Low-Income Community Projects

In the final Clean Power Plan EGs, the EPA expressed its intent to divide the matching pool of 300 million short tons of CO_2 emissions into a RE reserve for wind and solar projects, and a reserve for low-income demand-side EE projects, (80 FR 64829, October 23, 2015). As presented in section III.C of this preamble, in this action, the EPA is proposing that the RE reserve would also accommodate CEIP awards (on a one-to-one basis) to geothermal and hydropower projects and that the low-income community reserve would also accommodate CEIP awards (on a two-to-one basis) to solar projects implemented to serve low-income communities. After taking account of this proposal to include geothermal and hydropower projects as eligible for the RE reserve, and solar projects implemented to serve low-income communities as eligible for the low-income community reserve, the EPA is proposing, consistent with the intent stated in the final Clean Power Plan EGs, that the matching pool be divided evenly between the two reserves, with 50 percent of the matching pool (150 million allowances, or 187.5 million ERCs) made available for eligible CEIP RE projects and 50 percent of the matching pool (150 million allowances, or 187.5 million ERCs) made available for eligible CEIP low-income community projects.

The EPA is proposing that a CEIP-participating state may allocate early action allowances or issue early action ERCs up to an amount equivalent to the number of matching allowances or matching ERCs the state is eligible to receive from the EPA for each reserve, as listed in tables 1 and 2 of this preamble. Allowances or ERCs that are designated for one reserve may not be re-designated for the other reserve, (*e.g.*, allowances that are reserved for low-income community projects may not be reallocated to the RE reserve or vice versa).

The proposal for the 50 percent/50 percent apportionment is based in part upon the EPA's analysis of the potential MWh that may be achieved by wind, solar, geothermal, hydropower, and low-income EE projects in 2020 and 2021, as well as upon stakeholder feedback regarding the appropriate apportionment between these two reserves.

As discussed in section III.C of this preamble, the EPA is proposing to replace the term "commence construction" for CEIP-eligible RE projects with the term "commence commercial operation," as well as to make an associated change in the date of project eligibility to on or after January 1, 2020. The EPA is not reopening the decision to set the size of the CEIP matching pool at 300 million short tons. However, we note that even under the proposed changes to project eligibility, and the updated assumptions as discussed in the TSD to this action titled "Renewable Energy and Low Income Energy Efficiency Potential," the EPA projects that energy generation from potentially eligible CEIP wind, solar, geothermal and hydropower projects will not exceed 400 million MWh in 2020 and 2021 combined. Thus, even if the EPA were considering a change in the magnitude of the CEIP (which it is not), new information and assumptions at this point would not lead the Agency to a different result in terms of the appropriate size of the CEIP matching pool, in light of the objectives for the CEIP identified in the final EGs, 80 FR at 64829–64832.

Further, the EPA proposes, in line with the discussion in the final EGs, that 50 percent of the matching pool would be the appropriate amount to apportion to the RE reserve. With regard to wind and solar potentials, at the time of promulgation of the Clean Power Plan EGs, the EPA projected that the deployment rates for wind and solar energy would remain relatively modest in the years leading up to the start of the interim plan performance period (*i.e.*, no greater than the combined historic maximum deployment rates experienced for wind in 2012 and for solar in 2014).[28] Subsequent to finalization of the CPP, Congress extended tax credits for wind and solar resources. It is likely that the extension of the wind and solar tax credits in December 2015, as well as the May 5, 2016 IRS guidelines extending the Production Tax Credit (PTC) Continuity Safe Harbor from 2 years to 4 years, may also impact the development of wind and solar projects that commence commercial operation in 2020 onward.[29] Nonetheless, the EPA continues to believe that one half of the total size of the CEIP matching pool remains the appropriate amount to incentivize the qualifying RE technologies—wind, solar, geothermal and hydropower—in light of the multiple purposes and scale of the CEIP.

At the same time, the EPA believes that the remaining 50 percent of the CEIP matching pool remains the appropriate size for the low-income community reserve, leaving a more-than adequate margin to accommodate large-scale deployment of both demand-side EE projects and solar projects implemented to serve low-income communities. As discussed in section III.C of this preamble, the EPA is proposing to clarify the term "commence operation" for CEIP-eligible low-income demand-side EE projects, and to make a change in the date of eligibility for such projects such that they may commence operation on or after September 6, 2018. In addition, also as discussed in section III.C of this preamble, the EPA is proposing to replace the term "commence construction" for CEIP-eligible RE projects (including solar projects implemented to serve low-income communities) with the term "commence commercial operation" and to make an associated change in the eligibility date for such projects to January 1, 2020.[30]

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[28] See TSD to the Final Clean Power Plan titled "Greenhouse Gas Mitigation Measures," Docket ID No. EPA–HQ–OAR–2013–0602.

[29] *See:* Consolidated Appropriations Act, 2016 (H.R. 2029, Sec. 301 and Sec. 303) (Dec. 18, 2015). This legislation extended the expiration date for the Production Tax Credit (PTC) for qualified facilities that use wind to produce electricity, as well as permission for PTC-eligible wind facilities to claim the Investment Tax Credit (ITC) in lieu of the PTC, through the end of 2019 (Sec. 301). The Act also extended the expiration date for the ITC tax credit for qualified solar energy equipment that generates electricity until January 2, 2022 (Sec. 303). *See also:* Internal Revenue Service Notice 2016–31, May 5, 2016.

[30] As explained above in Section II.B, the decision not to propose further changes to the key timing elements of the CEIP in this action should not be taken to indicate any particular view or intention by the Agency regarding how the timelines for the Clean Power Plan overall may be impacted by the Supreme Court's stay.

Given these assumptions, and also as explained in detail in the TSD to this action titled "Renewable Energy and Low Income Energy Efficiency Potential," the EPA estimates that energy savings from potentially eligible CEIP low-income demand-side EE projects could reach up to 39 million MWh in 2020 and 2021 combined, thus absorbing approximately ten percent of the matching allowances or ERCs provided by the EPA in the matching pool. The EPA estimates that generation from solar projects implemented to serve low-income communities could reach up to 8 million MWh in 2020 and 2021 combined, thus absorbing approximately an additional two percent of the matching allowances or ERCs provided by the EPA in the matching pool.

Given that eligible low-income community projects may receive CEIP awards on a two MWh to one MWh basis (as discussed in section III.A of this preamble), with half of the award coming from the state, and half of the award coming from the EPA, these 39 million MWh of low-income energy efficiency savings and 8 million MWh of solar generation implemented to serve low-income communities would be eligible to receive approximately 47 million matching ERCs, or 38 million matching allowances.

In light of this analysis, and in agreement with stakeholder comment that the EPA should apportion the matching allowances and ERCs evenly between a reserve for RE projects and a reserve for low-income community projects, the EPA is proposing that the matching pool be divided evenly between the two reserves, with 50 percent of the matching pool (150 million allowances, or 187.5 million ERCs) made available for RE projects and 50 percent of the matching pool (150 million allowances, or 187.5 million ERCs) made available for low-income community projects.

This apportionment is appropriate for several policy and technology-driven reasons. The apportionment achieves the policy objective of the CEIP, which is to ensure incentives for deployment of additional projects in both reserves (RE projects as well as low-income community projects). Whereas some stakeholders requested that we apportion the matching pool such that low-income community projects be eligible to receive more than 50 percent of the matching pool, our analyses do not support the need for a reserve for low-income community projects larger than 150 million allowances/187.5 million ERCs in order to meet demand during the CEIP period, even with the two-to-one award for such projects. However, the EPA requests information and data that may support a larger reserve for low-income community projects.

The proposal would also add solar projects implemented to serve low-income communities as eligible low-income community CEIP projects. This expansion of the CEIP scope in low-income communities promotes emission reductions and will help these communities better harness the benefits of energy efficiency and solar resources. More specifically, this expansion of the CEIP scope will provide low-income communities a greater opportunity to reach the full scale of opportunity presented by the reserve of matching allowances and ERCs for low-income community projects.

The EPA further believes that the 50-50 apportionment is an appropriate choice based on the rapidly evolving pace of technology and consumer demand for energy in the United States. Several analysts have noted that the electric power sector will undergo transformative changes from a number of factors, particularly lower costs for distributed generation, technology improvements in RE resources, and rapid innovation in energy efficiency technologies (*e.g.*, lighting and temperature controls). For example, a 2016 first quarter update from the Federal Energy Regulatory Commission (FERC) shows that RE made up almost all new capacity added in the United States so far this year—constituting 99% of the new generation capacity in service.[31] These changes are occurring at a rapid pace and support the view that the CEIP apportionment should provide incentives and room for continued growth in both renewables and energy efficiency projects in low-income communities.

The apportionment of the two reserves, on a state-by-state basis, is included in tables 1 and 2.[32] The EPA further proposes that a state may not transfer matching allowances or ERCs between these two reserves in its state-level apportionment. In other words, should one reserve become fully subscribed, the state would not be permitted to move matching allowances or ERCs into it from the other reserve. Rather, as stated in the Clean Power Plan EGs, the EPA will retire matching allowances or ERCs that remain in each of the state's two reserves following January 1, 2023 (See 80 FR 64803, October 23, 2015). Such a retirement is appropriate given that the intent of the matching pool is to incentivize early actions in 2020 and 2021, and matching allowances and ERCs in this pool should not be available to award to actions from 2022 onward, during the performance periods under the Clean Power Plan EGs.

The EPA seeks comment on all aspects of the proposed 50 percent/50 percent division of the 300 million short ton matching pool into a reserve for RE projects and a reserve for low-income community projects. In particular, the EPA seeks comment on the extent to which the recent extension of the federal tax credits for wind and solar resources will help to meet the CEIP's objectives with respect to promoting increased deployment of RE resources, including wind and solar, over the period leading up to 2022. The EPA notes that DOE's National Renewable Energy Laboratory has published an analysis which found that with these tax credits in place, roughly 100 gigawatts of additional wind and solar capacity would be added by the end of 2021.[33] Similar analyses have been conducted by third parties. Therefore, the EPA seeks comment on whether it is appropriate, in light of the tax credit extensions, to include in the CEIP a mechanism that would limit the number of early action and matching allowances or ERCs that may be available to wind and solar projects that may not require additional incentives for deployment, and on how to best design such a mechanism.[34] One potential approach would be to apportion less than 50 percent (*e.g.*, 30 percent or 25 percent) of the 300 million short ton matching pool to the reserve for eligible RE projects. Some stakeholders have suggested that another approach would be to exclude projects from CEIP eligibility that are benefitting from the Investment Tax Credit (ITC) or PTC from CEIP eligibility. In response to this stakeholder feedback, we request comment on whether and how to implement limitations on CEIP participation for wind and solar resources that benefit from the ITC or PTC. For example, a state could request, as part of a wind or solar project's CEIP eligibility application that it submit a certification that it is not benefitting from the PTC or ITC. Further the EPA seeks comment on whether the project should still be allowed to receive CEIP awards if it only receives a partial tax credit. The EPA seeks comment on this and other approaches a state could use to ensure that a wind or solar project submitting an eligibility application for a CEIP award is not also receiving tax incentives. We also solicit comment on whether and how any considerations of impacts of the PTC or ITC should impact apportionment for the RE reserve. The EPA is also seeking comment on an alternative apportionment of the reserves, which would set a "floor" on the portion of the matching pool that would be available for RE projects and low-income community projects and leave a portion of the matching pool available to be apportioned at the states' discretion. For example, 40 percent of every state's pro rata share could be reserved for RE projects and 40 percent could be reserved for low-income community projects, with the remaining 20 percent to be awarded at the state's discretion to any CEIP-eligible project type.

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[31] Federal Energy Regulatory Commission (FERC). March 2016. Energy Infrastructure Update; Office of Energy Projects. Page 4. Accessed on June 14 at *http://www.ferc.gov/legal/staff-reports/2016/mar-infrastructure.pdf.*

[32] In section III.D of this preamble, we discuss potential participation options for noncontiguous states and territories and for tribes without affected EGUs. Pro rata shares proposed in this action do not reflect potential shares that may be apportioned to these groups pending comments.

[33] *http://www.nrel.gov/docs/fy16osti/65571.pdf.*

[34] The EPA acknowledges that geothermal technologies are eligible for a permanent 10 percent tax credit. However, because analysis indicates that these technologies will likely not be widely deployed during the 2020–2021 timeframe, we do not believe it is necessary to constrain the number of early action and matching allowances or ERCs that may be available to geothermal projects. For a projection of constant geothermal generation in 2020 and 2021, see *http://www.eia.gov/forecasts/aeo/data/browser/<#/?id=16-AEO2016&cases=ref2016~ref_no_cpp&sourcekey=0.*

4. Apportionment of the Matching Pool Among the States: Allowances and ERCs Available in the RE and Low-Income Community Reserves

The final Clean Power Plan EGs expressed the EPA's intent to apportion the 300 million ton matching pool among states based on the amount of reductions from 2012 levels the affected EGUs in the state are required to achieve relative to those in other participating states (80 FR 64830, October 23, 2015). Tables 1 and 2 show the state-level shares that result from this calculation approach, including the number of allowances (of the 300 million allowance total) or ERCs (of the 375 million ERC total) that would be available to a CEIP-participating state depending on the choice of a mass-based or rate-based state plan. See the TSD to this action, titled "Apportionment of the Matching Pool among the States," for further discussion of the calculation approach.

As discussed in section III.A, the EPA proposes to divide each state's share of the matching pool into a portion for RE projects and a portion for low-income community projects. An apportionment between the two reserves of 50 percent for RE and 50 percent for low-income community projects is shown in tables 1 and 2 of this preamble. The EPA is proposing that only those states with EGUs subject to the final Clean Power Plan EGs and that have submitted a final plan with approved CEIP provisions, as well as those states for whom the EPA may implement a federal plan, will receive an apportionment of the matching pool that the EPA is making available under the CEIP.[35] However, we do note that eligible projects outside of the boundaries of CEIP-participating states may still be eligible for award of early action and matching allowances or ERCs, so long as that project provides a benefit to the state issuing the award.

TABLE 1—PROPOSED STATE SHARES OF MATCHING POOL

[Allowances][36]

State/tribe	Available matching allowances (mass-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total share (100%)
Alabama	4,683,458	4,683,458	9,366,916
Arizona	2,579,426	2,579,426	5,158,852
Arkansas	3,280,844	3,280,844	6,561,688
California	328,268	328,268	656,536
Colorado	3,334,788	3,334,788	6,669,576
Connecticut	104,122	104,122	208,244
Delaware	207,588	207,588	415,176
Florida	4,845,372	4,845,372	9,690,744
Georgia	4,133,434	4,133,434	8,266,868
Idaho	22,392	22,392	44,784
Illinois	8,953,081	8,953,081	17,906,162
Indiana	8,631,114	8,631,114	17,262,228
Iowa	3,286,774	3,286,774	6,573,548
Kansas	3,173,445	3,173,445	6,346,890
Kentucky	7,429,292	7,429,292	14,858,584
Lands of the Fort Mojave Tribe	8,827	8,827	17,654
Lands of the Navajo Nation	2,434,598	2,434,598	4,869,196
Lands of the Uintah and Ouray Reservation	263,264	263,264	526,528
Louisiana	2,246,141	2,246,141	4,492,282
Maine	31,109	31,109	62,218
Maryland	1,459,162	1,459,162	2,918,324
Massachusetts	255,705	255,705	511,410
Michigan	5,591,791	5,591,791	11,183,582
Minnesota	3,004,354	3,004,354	6,008,708

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[35] See section III.D for a discussion of pathways by which tribes and states without affected EGUs, as well as states and territories for which the EPA has not yet finalized emission goals under the Clean Power Plan, may participate in the CEIP.

[36] As discussed in section III.D of this document, shares that may be provided to states and territories where goals have yet to be established would be distributed from the 300 million short ton matching pool, if the Agency moves forward with those options. Once the values for these shares are determined, if at all, table 1 would be updated to reflect the shares for all states, territories and tribes receiving CEIP matching allowances. We anticipate that the overall total share of the CEIP matching pool needed for states and territories where goals have yet to be established would be no more than five percent of the total pool (or about 15 million allowances).

TABLE 1—PROPOSED STATE SHARES OF MATCHING POOL—Continued

[Allowances][36]

State/tribe	Available matching allowances (mass-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total share (100%)
Mississippi	535,959	535,959	1,071,918
Missouri	5,656,983	5,656,983	11,313,966
Montana	1,965,515	1,965,515	3,931,030
Nebraska	2,222,542	2,222,542	4,445,084
Nevada	504,431	504,431	1,008,862
New Hampshire	161,696	161,696	323,392
New Jersey	669,007	669,007	1,338,014
New Mexico	1,234,572	1,234,572	2,469,144
New York	836,656	836,656	1,673,312
North Carolina	4,011,884	4,011,884	8,023,768
North Dakota	3,225,953	3,225,953	6,451,906
Ohio	7,182,558	7,182,558	14,365,116
Oklahoma	3,100,508	3,100,508	6,201,016
Oregon	231,529	231,529	463,058
Pennsylvania	7,559,018	7,559,018	15,118,036
Rhode Island	53,511	53,511	107,022
South Carolina	2,479,202	2,479,202	4,958,404
South Dakota	396,310	396,310	792,620
Tennessee	3,267,125	3,267,125	6,534,250
Texas	15,600,288	15,600,288	31,200,576
Utah	2,101,783	2,101,783	4,203,566
Virginia	2,079,819	2,079,819	4,159,638
Washington	1,127,151	1,127,151	2,254,302
West Virginia	5,260,335	5,260,335	10,520,670
Wisconsin	3,590,805	3,590,805	7,181,610
Wyoming	4,656,486	4,656,486	9,312,972
Total	149,999,975	149,999,975	299,999,950

TABLE 2—PROPOSED STATE SHARES OF MATCHING POOL

[Emission rate credits][37]

State/tribe	Available matching ERCs (rate-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total share (100%)
Alabama	5,854,323	5,854,323	11,708,646
Arizona	3,224,283	3,224,283	6,448,566
Arkansas	4,101,055	4,101,055	8,202,110
California	410,335	410,335	820,670
Colorado	4,168,485	4,168,485	8,336,970
Connecticut	130,153	130,153	260,306
Delaware	259,485	259,485	518,970
Florida	6,056,715	6,056,715	12,113,430
Georgia	5,166,792	5,166,792	10,333,584
Idaho	27,991	27,991	55,982
Illinois	11,191,352	11,191,352	22,382,704
Indiana	10,788,892	10,788,892	21,577,784
Iowa	4,108,467	4,108,467	8,216,934
Kansas	3,966,806	3,966,806	7,933,612
Kentucky	9,286,616	9,286,616	18,573,232
Lands of the Fort Mojave Tribe	11,034	11,034	22,068
Lands of the Navajo Nation	3,043,247	3,043,247	6,086,494
Lands of the Uintah and Ouray Reservation	329,080	329,080	658,160
Louisiana	2,807,677	2,807,677	5,615,354
Maine	38,886	38,886	77,772
Maryland	1,823,952	1,823,952	3,647,904
Massachusetts	319,632	319,632	639,264
Michigan	6,989,739	6,989,739	13,979,478
Minnesota	3,755,443	3,755,443	7,510,886
Mississippi	669,949	669,949	1,339,898

TABLE 2—PROPOSED STATE SHARES OF MATCHING POOL—Continued

[Emission rate credits][37]

State/tribe	Available matching ERCs (rate-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total share (100%)
Missouri	7,071,229	7,071,229	14,142,458
Montana	2,456,894	2,456,894	4,913,788
Nebraska	2,778,178	2,778,178	5,556,356
Nevada	630,539	630,539	1,261,078
New Hampshire	202,121	202,121	404,242
New Jersey	836,258	836,258	1,672,516
New Mexico	1,543,216	1,543,216	3,086,432
New York	1,045,820	1,045,820	2,091,640
North Carolina	5,014,855	5,014,855	10,029,710
North Dakota	4,032,441	4,032,441	8,064,882
Ohio	8,978,197	8,978,197	17,956,394
Oklahoma	3,875,635	3,875,635	7,751,270
Oregon	289,411	289,411	578,822
Pennsylvania	9,448,773	9,448,773	18,897,546
Rhode Island	66,889	66,889	133,778
South Carolina	3,099,003	3,099,003	6,198,006
South Dakota	495,387	495,387	990,774
Tennessee	4,083,907	4,083,907	8,167,814
Texas	19,500,360	19,500,360	39,000,720
Utah	2,627,229	2,627,229	5,254,458
Virginia	2,599,773	2,599,773	5,199,546
Washington	1,408,939	1,408,939	2,817,878
West Virginia	6,575,419	6,575,419	13,150,838
Wisconsin	4,488,506	4,488,506	8,977,012
Wyoming	5,820,607	5,820,607	11,641,214
Total	187,499,975	187,499,975	374,999,950

5. Provisions for Reapportioning Matching Allowances and ERCs Among CEIP-Participating States

The preamble to the final Clean Power Plan EGs indicated that, following receipt of final state plans, the EPA would execute a reapportionment of matching allowances or ERCs among the states, if it proves necessary. However, some stakeholders during the informal outreach period raised concerns around the timing in which the EPA would know that additional matching allowances or ERCs are available for reapportionment and whether a later reapportionment would be capable of addressing remaining unmet-demand for eligible CEIP projects. The EPA agrees that timing considerations may create a degree of uncertainty that makes reapportionment among states inappropriate. Additionally, as discussed in section III.A, the wind and solar tax credit extensions could also impact the imperative for reapportionment. Therefore, the EPA is not including reapportionment provisions in the CEIP.

The EPA also recognizes that there may be administrative challenges that may not support reapportioning of matching allowance/ERCs to states participating in the CEIP. From an administrative perspective, reapportioning CEIP allowances/ERCs after the known CEIP participants are determined, but before the CEIP program begins, may not be feasible depending on when state plans are submitted and approved, including approvable CEIP provisions. In addition, if a reapportionment were to occur, it could occur when the state has already begun to implement its CEIP, thus providing an element of uncertainty for states and project providers.

Reapportionment of matching allowances/ERCs may also influence a state's decision to opt-in to the CEIP, based on considerations that neighboring states could receive additional matching allowances/ERCs if the state chooses not to opt-in to the program. This could be perceived as a 'double-disadvantage': Not only is the state electing to not receive matching allowances/ERCs, it is also electing to have other states' matching allowance/ERC shares increased. This consideration could lead to a perverse incentive for a state to opt-in to the program in an effort to shield their original share of the matching pool from reapportionment, but not follow through on program implementation. Lastly, the EPA expects that most states will opt to take advantage of the benefits provided by the CEIP, and therefore as such, do not expect a large pool of remaining matching allowances or ERCs would be available for reapportionment. In lieu of reapportioning matching allowances or matching ERCs that are not claimed by a state that chooses not to opt-in to the CEIP, the EPA would simply retire these unclaimed matching allowances or ERCs on January 1, 2023.

Although we are not including reapportionment provisions in this proposal, we are seeking comment on whether these provisions should be included. In the case of reapportionment, only those states with approved state plans that include approved CEIP provisions, and states for whom the EPA is implementing the federal plan, would be eligible to receive a final apportionment of matching allowances or ERCs from the EPA. States that choose not to participate in the CEIP, or states with approved state plans that do not contain approved CEIP provisions, would not be eligible to receive an apportionment. If a state elects not to participate in the CEIP or the CEIP provisions of a state's approved state plan are disapproved, the matching allowances or ERCs listed for that state in tables 1 and 2 of this preamble would be reapportioned to the other states that are participating in the CEIP via an approved state plan with approved CEIP provisions, or via a federal plan. This reapportionment would be executed on a pro-rata basis, using the same calculation method used to establish the initial apportionment of matching allowances/ERCs among the states.[38] Any matching allowances or ERCs that were not awarded from a state's matching allowance or ERC apportionment by January 1, 2023 would be retired by the EPA. The EPA requests comment on whether to include reapportionment provisions, and the methodology that should be used for reapportioning matching allowances or ERCs.

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[37] As discussed in section III.D of this document, shares that may be provided to states and territories where goals have yet to be established would be distributed from the 300 million short ton matching pool, if the Agency moves forward with those options. Once the values for these shares are determined, if at all, table 2 would be updated to reflect the shares for all states, territories and tribes receiving CEIP matching ERCs. We anticipate that the overall total share of the CEIP matching pool needed for states and territories where goals have yet to be established would be no more than five percent of the total pool (or about 18.75 million ERCs).

B. Requirements for States That Choose to Participate in the CEIP

State plans that include implementation of the CEIP must meet certain requirements to ensure effective administration of the state's CEIP. Several basic requirements have already been established in the final EGs at 40 CFR 60.5737. This section summarizes those requirements and also proposes additional requirements necessary for implementation of a state CEIP and the related award of EPA matching allowances or ERCs. This section also discusses relevant proposed optional example rule provisions for the CEIP, which would constitute a presumptively approvable approach for meeting these CEIP requirements.[39] In the discussion that follows, we present requirements for allocation of early action allowances or issuance of early action ERCs by a state. Section III.B.2 discusses a proposed process by which EPA matching allowances or ERCs would be awarded. Section III.B.3 reviews the requirement finalized in the Clean Power Plan EGs to maintain the stringency of mass-based or rate-based CO_2 emission performance by affected EGUs when implementing the CEIP, and proposes a method for meeting this requirement for mass-based plans and rate-based plans. Section III.B.4 proposes how states may define "low-income community" for purposes of implementing the CEIP. Section III.B.5 proposes requirements for addressing potential improper allocation or issuance of early action allowances or early action ERCs, respectively.

1. State Plan Requirements for Distribution of Early Action Allowances or ERCs

A state plan that implements the CEIP must include requirements that specify the process for application for, and allocation/issuance of, early action allowances or ERCs under the CEIP, as applicable.[40] [41] Many of these requirements were included in the final EGs at 40 CFR 60.5737, and unless otherwise noted, this action does not re-open these requirements. (We discuss these requirements solely to help identify what new or revised requirements we are proposing, and to provide an overall view of all the requirements.) However, this action proposes several changes and enhancements to these requirements. If the changes proposed in this action are finalized, then taken together, these requirements would include:

—Eligibility requirements for projects under the CEIP, including the definition(s) of low-income community a state intends to use to make CEIP awards to low-income community projects;

—Requirements for submission of project eligibility[42] applications to the state for the allocation/issuance of early action allowances or early action ERCs, demonstrating the eligibility of the project under the CEIP, including an EM&V plan for the project;

—Requirements for submission of M&V reports to the state, containing monitored and verified MWh generation or savings results for a project;

—Requirements for submission of accompanying verification reports by an accredited independent verifier, for both eligibility applications and M&V reports;[43]

—Requirements for accreditation of independent verifiers and conduct of independent verifiers;

—State allocation or issuance of early action allowances or early action ERCs, based on quantified and verified MWh;

—Tracking system capabilities and infrastructure necessary to support state administration of the CEIP;[44]

—Actions to be taken if early action allowances or early action ERCs are found to have been improperly issued;

—A mechanism for ensuring maintenance of CO_2 emission performance by affected EGUs, considering state implementation of the CEIP;[45]

We note the requirement in the final EGs, which we are not reopening, that if a final state plan includes CEIP provisions, the entire plan, including the CEIP, is subject to the requirements for meaningful engagement and public comment. In addition, the EPA is proposing in this action that a state plan must not prohibit an eligible CEIP project from receiving early action allowances or ERCs on the basis that the project is located in Indian country.

Many of the requirements listed previously were established in the final Clean Power Plan EGs (80 FR 64692). This proposal includes additions and revisions to certain requirements in the final Clean Power Plan EGs necessary to allow for implementation of the CEIP. This action proposes no changes to, and does not in any way re-open, any aspects of the final Clean Power Plan other than those expressly proposed or on which we expressly request comment, and all such potential changes are solely related to the CEIP. We are also proposing optional example regulatory text for the CEIP, which when finalized, would provide presumptively approvable approaches for implementing the CEIP by a state as part of a mass-based emission budget trading program or a rate-based emission trading program.[46] The EPA has structured the proposed optional example regulatory text for the CEIP in a manner that would enable it to be integrated with the proposed model trading rules for mass-based and rate-based emission trading programs.[47] The CEIP optional example regulatory text in this proposal replaces proposed provisions for the CEIP included in the October 23, 2015, model trading rules proposal. In addition, the EPA requests comment on utilizing this presumptively approvable optional example regulatory text as CEIP provisions under a federal plan.

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[38] See TSD titled "Apportionment of the Matching Pool among the States".

[39] The EPA requests comment on the use of the proposed optional CEIP example rule provisions as suitable regulatory text in the event of implementation of a federal plan CEIP.

[40] States with rate-based state plans would issue early action ERCs; states with mass-based state plans would allocate early action allowances.

[41] Consistent with provisions in the Clean Power Plan emissions guidelines at 80 FR 64906, section VIII.K.2.b, a state may empower an agent to act on its behalf when administering the CEIP. A state agent is a party acting on behalf of the state, based on authority vested in it by the state, pursuant to the legal authority of the state. A state could designate an agent to provide certain limited administrative services, or could choose to vest an agent with greater authority. Where an agent issues an ERC or allowance on behalf of the state, such issuance would have the same legal effect as issuance of an ERC or allowances by the state.

[42] CEIP-eligible project types are discussed in section III.C of this proposal.

[43] While submitted separately by an independent verifier, a verification report constitutes part of an eligibility application and M&V report.

[44] Following the proposal of the Clean Power Plan, the EPA received a number of comments from states and stakeholders about the value of the EPA's support in developing and/or administering tracking systems to support state administration of emission trading programs. The EPA is exploring options for providing such support and is conducting a scoping assessment of tracking system support needs and functionality. This scoping assessment will consider support that could assist states with implementation of the CEIP, should a state choose to include the CEIP in a state plan.

[45] As established in the Clean Power Plan EGs (and not re-opened here), any state that chooses to participate in the CEIP must demonstrate in its plan that it has a mechanism in place that enables issuance of early action ERCs or early action allowances in a manner that would have no impact on the aggregate emission performance of affected EGUs required to meet rate-based or mass-based CO_2 emission standards during the compliance periods (80 FR 64831). For a mass-based program, maintenance of stringency is addressed through the established emission budget for affected EGUs, as discussed in this section. The mechanism by which rate-based states may meet this requirement is discussed in this section.

As finalized in the Clean Power Plan EGs, states opting into the CEIP must include requirements in their plans for allocation or issuance of early action allowances or early action ERCs, respectively, that meet the requirements for the issuance of ERCs (see final rule preamble, section VIII.K.2, and regulatory text at 40 CFR 60.5737(e)). Such a requirement applies to both mass-based and rate-based state plans including the CEIP, as the CEIP is based on eligible MWh of energy savings or RE generation, and these MWh must be quantified and verified appropriately in order to demonstrate eligibility for awards of early action and matching allowances or ERCs. Where relevant, the proposed CEIP optional example regulatory text cross-references applicable provisions in the proposed mass-based and rate-based model trading rules, respectively, that address such requirements.[48] The EPA is proposing two sets of CEIP optional example regulatory text—one set of provisions for inclusion in a mass-based trading program, and one set of provisions for inclusion in a rate-based trading program. As a result, each set of proposed CEIP optional example regulatory text makes relevant cross references to provisions in the proposed mass-based and rate-based model trading rules. These cross references include references to provisions in the proposed mass-based and rate-based model trading rules that would, in the Agency's view (pending its review of public comments and ultimate finalization of the model trading rules), meet the requirements in the final EGs for the process for state issuance of ERCs. (The final EGs themselves are not re-opened with respect to the requirements for ERC issuance.) This includes provisions in the proposed mass-based and rate-based model trading rules that address: Requirements for eligibility applications (including EM&V plans),[49] EM&V requirements for different types of eligible projects and programs,[50] M&V reports,[51] verification reports (included with both eligibility applications and M&V reports), requirements for independent verifiers,[52] and provisions that address potential improper issuance of ERCs or improper allocation of allowances.[53]

The state plan requirements for implementation of the CEIP summarized previously apply regardless of whether a state is allocating early action allowances under a mass-based emission budget trading program or issuing early action ERCs under a rate-based emission trading program. In addition, these provisions must specify requirements for eligible projects under the CEIP, including the requirement that EE projects are implemented in "low-income communities."[54] These provisions must also include requirements for the quantification and verification of MWh results, as well as a two-step administrative process for determination of project eligibility and allocation or issuance of either early action allowances or ERCs. These requirements, for rate-based and mass-based programs, respectively, are discussed in the sections that follow.

a. Requirements for State Plans that Include Mass-Based Emission Budget Trading Programs

Where a state plan includes a mass-based emission budget trading program, the plan will need to include requirements that support the allocation of early action allowances under the state CEIP. A number of these are additional requirements that are not necessary under an approvable mass-based emission budget trading program that does not include a state CEIP. However, many of these additional requirements are similar to those that would be entailed for the administration of allowance set-asides to address potential leakage to new sources in the absence of the CEIP, if the state chooses such set-asides as the means for addressing potential leakage. In general, administering an allowance set-aside involves provisions to address entities that are eligible to receive allowances from a set-aside and specification of the method for allocating allowances from the set-aside. As a result, to the extent that a state decides to implement one or more allowance set-asides as part of its plan, even in the absence of the CEIP, a similar framework to the one summarized previously would likely be established in many cases.

These additional requirements include regulatory provisions that address the eligibility of resources for state allowance allocation under the CEIP, and the process for such allocation, including: Requirements for submission of eligibility applications, which include EM&V plans; requirements for EM&V; requirements for submission of periodic M&V reports; requirements for accreditation of independent verifiers; requirements for independent verifier reports (which must accompany both eligibility applications and M&V reports); and necessary tracking system capabilities that provide for the required two-step process for application for early action allowances that is consistent with the required two-step process for the issuance of ERCs.

In addition, the requirements for allocation of early action allowances under a state CEIP must include provisions for how allowances will be allocated based on the number of quantified and verified MWh reported by an eligible resource (*i.e.,* the MWh-to-allowance award ratios for CEIP-eligible RE, and low-income community projects). The EPA is proposing that early action allowances allocated under a state CEIP must be allocated in conformance with the provisions included in section III.A of this preamble.

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[46] While the proposed optional example regulatory text provides a presumptively approvable approach for a state's participation in the CEIP, the EPA recognizes that states may choose alternate approaches, provided they meet the requirements for CEIP participation included in amendments to the Clean Power Plan EGs included in this action, once finalized.

[47] 80 FR 64966–65116 (October 23, 2015)

[48] The cross-referenced provisions themselves are not re-proposed by this action.

[49] *See id.* at 64998.

[50] *See id.* at 65002.

[51] *See id.* at 65096.

[52] *See id.* at 65001.

[53] *See id.* at 64998.

[54] Section III.B discusses low-income definitions.

b. Requirements for State Plans that Include Rate-Based Emission Trading Programs

Where a state is implementing a rate-based emission trading program, the state plan will include necessary provisions for the issuance of ERCs, as previously described. These are the same requirements that are necessary to support state issuance of early action ERCs under the CEIP. As a result, the state plan would require limited additional requirements in order to implement the CEIP, beyond those required for a rate-based state plan in general. These additional requirements include provisions establishing the eligibility of projects under the CEIP and provisions to address maintenance of CO_2 emission performance by affected EGUs, as described in section III.B.3. In addition, an approvable state plan that includes a rate-based emission trading program will already include an identified tracking system that has the necessary capabilities and infrastructure to support the issuance of early action ERCs.

2. Process for the Award for EPA Matching Allowances or ERCs

The EPA is proposing that state plan requirements for the request of EPA matching allowances or ERCs must be consistent with the following process.

The EPA is proposing that it will establish an EPA matching allowance or ERC account for each state in the relevant tracking system for each state mass-based emission budget trading program (in the case of matching allowances) and rate-based emission trading program (in the case of matching ERCs). The EPA proposes to grant states the ability to transfer EPA matching allowances or ERCs from the EPA matching account, on behalf of the EPA, under the conditions described later in this preamble.

The state plan must specify the conditions under which the state will authorize such transfers of EPA matching allowances or ERCs from the EPA matching account to the designated account of an eligible CEIP project. Those state plan provisions must specify that a transfer of EPA matching allowances or ERCs may only occur subsequent to a state allocation or issuance of early action allowances or ERCs, in accordance with requirements for such state early action awards specified in the state plan; must be made in accordance with the award ratios established in the EGs (and specified in the state plan); and must correspond with the number of early action allowances or ERCs allocated or issued to an eligible CEIP project. The EPA is also proposing that, when awarding matching allowances or ERCs on behalf of the EPA, a state must assign a vintage for each awarded matching allowance or ERC that corresponds to the vintage of the related early action allowance or ERC on the basis of which the matching allowance or ERC was awarded.[55] The EPA requests comment on this provision.

The state plan must adequately describe how the tracking system used to administer the state mass-based emission budget trading program or rate-based emission trading program will provide transparent public access to transfers of EPA matching allowances or ERCs from the EPA matching account. This includes tracking system access to CEIP project documentation related to the state allocation or issuance of early action allowances or ERCs, respectively. Furthermore, the tracking system must provide a mechanism for tracking the awarded EPA matching allowances or ERCs back to the relevant CEIP project documentation, and documentation of the state award of early action allowances or ERCs for which the EPA matching award was made.[56] The EPA notes that such requirements are consistent with the tracking system requirements in the EGs for the issuance of ERCs. In addition, the EPA is proposing optional example regulatory text for the CEIP that specifies this required process under both a mass-based emission budget trading program and a rate-based emission trading program.

These state plan provisions must specify that the state will transfer EPA matching allowances or ERCs from the EPA matching account on a regular established schedule, and no sooner than 60 days from the date of the relevant state award of early action allowances or early action ERCs for an eligible CEIP project. Prior to this date, the EPA may place a hold on state transfers from the EPA matching account, if it has questions about the proper state allocation of early action allowances or issuance of early action ERCs consistent with the requirements and process established in the approved state plan, or if there is evidence of potential improper state awards. The EPA believes that this approach balances streamlined implementation of the CEIP with appropriate safeguards to ensure the integrity of the CEIP. The EPA requests comment on this provision to provide for a delay between allocation or issuance of early action allowances or ERCs and the award of matching allowances or ERCs.

3. Addressing Requirement To Maintain Stringency of Mass-Based or Rate-Based Emission Performance

The Clean Power Plan EGs require that states opting in to the CEIP include in their state plans a mechanism that ensures that the allocation of early action allowances or issuance of early action ERCs to CEIP-eligible parties will not impact the CO_2 emission performance of affected EGUs required to meet rate-based or mass-based CO_2 emission standards during the plan performance periods.[57] This mechanism is not required to account for matching ERCs or allowances that may be issued to the state by the EPA.[58] This section proposes approaches for such mechanisms, for both mass-based emission budget trading programs and rate-based emission trading programs. Several commenters provided suggestions for how to address stringency maintenance for early action allowances allocated or early action ERCs issued. Commenters generally supported the inclusion of requirements that stringency must be maintained. Several commenters stated that EPA should not adjust state goals during the compliance period as a mechanism for maintaining stringency and that doing so may be too complicated of a methodology. For rate-based plans, several commenters suggested that EPA include provisions that account for early action ERCs and either allow for retirement of ERCs that would have been issued during the compliance period or require a 'discounting' or adjustment factor be applied to ERCs issued during the compliance period.

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[55] For an ERC, "vintage" refers to the calendar year in which the MWh on which issuance of the ERC is based occurred. For an allowance, "vintage" refers to the emission budget year of the allowance. Both ERCs and allowances may be banked for future use without limitation, as established in the final CPP. Borrowing of allowances is not allowed under the final CPP. For allowances, this means that only allowances for budget years that fall within a current or past compliance period may be used to demonstrate compliance. Borrowing is also prohibited for ERCs, but is not relevant from a practical standpoint, as ERCs may only be issued after quantification and verification of MWh generation or savings. As a result, by default, borrowing of ERCs is not possible.

[56] This includes access to the eligibility application for the relevant CEIP resource, the relevant M&V report on which the state award of early action allowances or ERCs is based, related independent verifier reports (for the eligibility application and relevant M&V report), and documentation of the state award of early action allowances or ERCs.

[57] For a description of this requirement, see the preamble to the final Clean Power Plan EGs at 80 FR 64830–64831 and the final rulemaking regulatory text at 40 CFR 60.5737(c).

[58] In addition, for states adopting a state measures plan type, we note that the EGs require inclusion of a federally enforceable backstop and associated implementing measures such as triggers based on reported emissions. See 40 CFR 60.5740(a)(3)(i). The EPA is proposing here that any trigger for the backstop required by the EGs for a state measures plan would not need to include or account for emissions authorized per EPA-awarded matching allowances under the CEIP. The EPA solicits comments on this proposal and any alternatives.

a. Addressing Maintenance of Stringency for Mass-Based Programs

Addressing maintenance of stringency under a mass-based state plan is straightforward. A state must address this plan requirement by implementing the CEIP through an allowance set-aside from the established state emission budget. Since allowances are being distributed from a finite emission budget, allocation of allowances from that budget for CEIP early actions cannot result in an increase in the allowable CO_2 emissions from the fleet of affected EGUs when complying with their emission standards.[59] Stringency is therefore maintained by the structure of an emission budget trading program, because the emission budget is established under the state plan and early action allowances related to a state CEIP are allocated from that emission budget.[60] As a result, the state-established emission budget is not increased as a result of the state allocation of allowances from a CEIP set-aside. The EPA further proposes that early action allowances must be allocated only from a state's emission budget established for the first interim step plan performance period (*i.e.*, 2022–2024).

b. Addressing Maintenance of Stringency for Rate-Based Programs

For a rate-based emission trading program included in a state plan implementing the CEIP, addressing the plan requirement to maintain the stringency of CO_2 emission performance requires a different mechanism than that required under a mass-based program. The very nature of a rate-based approach, which does not limit total emissions, poses certain challenges for demonstrating that stringency will be maintained.

In this program context, the state is implementing the CEIP by issuing early action ERCs for MWh of generation or savings achieved by CEIP-eligible projects during 2020 and/or 2021, before the plan performance period begins in 2022.[61] These early action ERCs may be used by affected EGUs to comply with a rate-based CO_2 emission standard during the plan performance period.

State-issued early action ERCs for CEIP-eligible MWh generation or savings in 2020 and/or 2021 will result in a larger total number of potential ERCs available for use by affected EGUs than would have otherwise been available in the absence of the CEIP. As finalized in the EGs, a state plan must account for these early action ERCs during the plan performance period, or there will be an impact on the aggregate CO_2 emission performance achieved by affected EGUs during the plan performance period when complying with their rate-based CO_2 emission standards. For purposes of fulfilling this plan requirement, the EPA is proposing that, for each early action ERC a state issues under the CEIP, the state must, during the interim plan performance period, either permanently withhold (*i.e.*, not issue) one ERC for a quantified and verified MWh achieved by an eligible ERC resources, or permanently retire one unused ERC[62] such that it cannot be used for CPP compliance. Unless such an adjustment is applied during the plan performance period to account for the issuance of early action ERCs, this total increase in potential available ERCs would allow affected EGUs to emit more CO_2 than would occur through the application of the CO_2 emission performance levels or state rate-based CO_2 goal during the plan performance period beginning in 2022.

As described later in this preamble, the EPA is proposing a specific presumptively approvable approach that rate-based states opting in to the CEIP may choose to use to meet the plan requirement to maintain the stringency of CO_2 emission performance by affected EGUs. (The EPA anticipates that it would use this approach if the EPA were to implement the CEIP under a rate-based federal plan.) The EPA is also soliciting comment on other approaches that could be considered presumptively approvable in a rate-based state plan that includes the CEIP.

The proposed presumptively approvable approach is as follows: A rate-based state opting in to the CEIP would apply an adjustment factor to all quantified and verified MWh from eligible ERC resources that are achieved during the first interim step (2022–2024) of the plan performance period, to account for the number of early action ERCs issued by a state under the CEIP for MWh achieved during 2020 and/or 2021. The state would apply this adjustment factor to the quantified and verified MWh reported by each eligible ERC resource, regardless of whether that resource received early action ERCs under the CEIP. This presumptively approvable approach would enable a state to fully account for the issuance of early action ERCs during the first interim step (2022–2024) of the plan performance period (*i.e.*, the number of early action ERCs issued by the state would be equal to the number of quantified and verified MWh from eligible ERC resources for which ERCs would be permanently withheld during the first interim step of the plan performance period), and thus demonstrate that its state plan is maintaining the stringency of CO_2 emission performance by affected EGUs.

The adjustment factor to be used in the presumptively approvable approach is determined by the following equation:

$$\text{Adjustment Factor} = 1 - \frac{\text{State Issued CEIP Early Action ERCs} / \text{Adjustment Period}}{\text{Quantified \& Verified MWh During Reporting Year}}$$

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[59] Under an emission budget trading program, the emission standard that applies to an individual affected EGU is a requirement to surrender allowances equal to reported CO_2 emissions for a given compliance period. Allowances are generally allocated in an amount that equals the CO_2 emission budget (*i.e.*, the CO_2 emission constraint that applies to the combined group of affected EGUs subject to the program).

[60] To meet the requirement to maintain stringency, the state plan must allocate early action allowances from within the established emission budget. The state may not increase the budget.

[61] Outside the context of the CEIP, ERCs may only be issued by a state for MWh of generation or savings by eligible resources that occur in 2022 and subsequent years (*i.e.*, during the plan performance period). Thus, in contrast with the discretion available to states implementing a mass-based program to allocate allowances for early action outside the context of the CEIP (though without the availability of any EPA matching allowances), states implementing a rate-based program may not issue ERCs for early action other than through the CEIP. This result is a natural consequence of the requirements for eligible resources that can be issued ERCs established in 40 CFR 60.5800 and is not open for comment in this action.

[62] ERCs that can be retired for this purpose may be produced by eligible ERC resources within the state or in other states that share the same rate-based approach (*i.e.* CO_2 emission performance levels or a state rate-based CO_2 goal). They may also be early action ERCs issued under the CEIP.

Where:

- State-Issued CEIP Early Action ERCs = the total number of early action ERCs issued by a state under the CEIP, for eligible MWh achieved in 2020 and/or 2021
- Adjustment Period = 3, the number of years in the first interim step of the plan performance period (2022–2024), to which the adjustment factor will be applied to address maintenance of CO_2 emission performance stringency
- Quantified and Verified MWh During Reporting Year = The total number of quantified and verified MWh reported by all eligible ERC resources to a state for a specific year of the first interim step of the plan performance period (2022–2024)

This equation calculates the adjustment factor (a fraction) that a rate-based state opting in to the CEIP would apply to the total quantified and verified MWh reported to that state by each individual eligible ERC resource for actions undertaken during the first interim step of the plan performance period (2022–2024). Once applied, this factor "adjusts" the number of ERCs that an eligible ERC resource may receive for actions undertaken during the first interim step of the plan performance period, to account for the early action ERCs the state issued to CEIP-eligible providers for MWh achieved in 2020 and/or 2021.

The following is an example calculation of the adjustment factor, for a scenario that assumes that 300 early action ERCs are issued by a state under the CEIP, and that, during the year 2022 (the first year of the first interim step period), all eligible ERC resources report 1,000 MWh to the state:

$$\text{Adjustment Factor} = 1 - \frac{300/3}{1{,}000} = 0.9$$

Based on application of the adjustment factor, each eligible ERC resource would receive a number of ERCs equal to the MWh it reported, multiplied by the adjustment factor of 0.9. In aggregate, all eligible ERC resources would receive 900 ERCs total for the 1,000 MWh total they reported in 2022.[63] The 100 MWh of quantified and verified MWh achieved by the eligible ERC resources, but for which the state did not issue ERCs, are applied toward the state's demonstration that it maintained the stringency of rate-based CO_2 emission performance during 2022.

This proposed presumptively approvable approach for maintaining stringency in a rate-based program provides a number of advantages. First, the approach provides a transparent way of demonstrating that the number of ERCs issued by a state under the CEIP is being fully accounted for during the plan performance period. Second, the proposed approach applies the same adjustment factor to all eligible ERC resources. This approach would provide greater assurance that early action ERCs are fully accounted for during the plan performance period than if an adjustment was only applied to the eligible ERC resources that received early action ERCs. It is uncertain that there would be sufficient MWh of energy generation or savings achieved by these resources during the plan performance period to fully account for the early action ERCs that were issued to those individual CEIP projects and providers.[64] Third, this approach would not substantially dilute the incentive provided to eligible resources that receive early action ERCs, in keeping with the goal of the CEIP to drive early action.

The EPA understands that there is a potential disadvantage to this approach. This method of applying the adjustment factor to all eligible ERC resources would reduce the number of ERCs issued to eligible ERC resources that did not participate in the CEIP, relative to their total quantified and verified MWh during the plan performance period. These eligible ERC resources would not have received early action incentives through the CEIP, yet would see a reduction in the potential incentives they could receive during the plan performance period. Nonetheless, the EPA also notes that such an incentive structure could provide further encouragement for projects and programs to participate in the CEIP, if it were implemented through a state plan.

The EPA seeks comment on this proposed presumptively approvable approach, including the timing for and duration of the adjustment period to be incorporated into the adjustment factor equation. The EPA also requests comment on alternative approaches the agency could consider as presumptively approvable methods to maintain the stringency of CO_2 emission performance achieved by affected EGUs during the plan performance period under a rate-based emission trading program that includes the CEIP. These could include approaches by which a state would withhold or retire ERCs during the first interim step of the plan performance period in an amount equal to the number of early action ERCs issued by the state under the CEIP for MWh achieved during 2020 and/or 2021. Additionally, we request information on mechanisms for ensuring that stringency is met with any alternative presumptively approvable approaches suggested.

4. Requirement To Establish a Definition of "Low-Income Community" for Purposes of Implementing the CEIP

A key element of the CEIP as finalized in the EGs is the establishment of incentives specific to projects implemented in low-income communities. As discussed in the final EGs, the additional incentive offered for low-income community projects is an effort to help overcome historical barriers to the deployment of energy efficiency projects in low-income communities (80 FR 64831). Incentivizing these projects will place affected EGUs in a better position to meet their emission reduction obligations under the EGs and improve the cost of implementation of the EGs, consistent with Congress' design in section 111 of the CAA. At the same time, the Agency believes that a focus on low-income communities will also deliver economic and environmental benefits to a more expansive set of underserved populations, including low-income, minority and tribal communities.[65]

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[63] If application of the adjustment factor resulted in a total calculated number of MWh that ends with a fractional value of a MWh remaining (*e.g.*, 900.7 MWh), the EPA is proposing that the number of MWh for which ERCs may be issued would be rounded down to the nearest integer (*e.g.*, 900). Such rounding is necessary, as ERCs may only be issued in whole MWh increments.

[64] The ongoing operation of individual projects or programs that are eligible for issuance of ERCs is subject to uncertainty. Projects or programs might be terminated, or might choose to suspend their application for the issuance of ERCs going forward, for multiple potential reasons unrelated to a state plan. Furthermore, the quantified and verified MWh of electricity generation or savings from an individual project or program could vary significantly from year to year, for a number of potential reasons. Therefore, it is uncertain that the projects or programs that received early action ERCs under the CEIP would cumulatively report quantified and verified MWh during the first 3 years of the plan performance period equal to or greater than the number of quantified and verified MWh reported for 2020 and 2021.

Proposing how states may develop their definition of "low income community" is a critical part of this action. In the context of the CEIP, the EPA is interpreting the term "community" in a manner consistent with the Council on Environmental Quality's *Environmental Justice Guidance Under the National Environmental Policy Act* which states "In identifying low-income populations, agencies may consider as a community either a group of individuals living in geographic proximity to one another, or a set of individuals . . . where either type of group experiences common conditions of environmental exposure or effect." [66]

In establishing requirements for a definition of "low-income community," the EPA considered several key principles. One principle is a desire to establish requirements that are clear and easy for states to implement as they develop their plans. The EPA believes that use of existing federal, state, and local definitions will provide the most clarity and ease of implementation. Another principle for the Agency is that a state's definition should provide transparency and consistency for all stakeholders with an interest in the CEIP, including project providers and communities that may benefit from implementation of CEIP-eligible projects. To further these principles, the EPA emphasizes that, by establishing clear definitions for a "low-income community" in the state plan, a state can make the process easier to implement and more transparent for all parties. Additional guidance on low-income community project eligibility is discussed in section III.C of this preamble.

A state plan that includes implementation of the CEIP must establish eligibility requirements for projects under the CEIP, including a requirement that eligible CEIP low-income community projects must be implemented in a low-income community.[67] We propose that a state choosing to participate in the CEIP must include in its state plan one or more definitions of low-income community that the state will apply to evaluate whether proposed EE and solar projects are implemented in low-income communities in that state. During the public outreach sessions for the CEIP and the comment period for the CEIP non-regulatory docket, the EPA heard from many commenters who supported enabling states to use existing low-income definitions, allowing both geographic and household-based definitions, allowing flexibility to address rural and urban areas of each state, and recognizing the existing public benefit programs being run by states and utilities.[68] The EPA agrees with those commenters. Due to the short-term (two-year) nature of the CEIP, and since existing program providers have experience with evaluating and implementing EE and RE projects in low-income communities, the EPA recognizes the value of building on successful existing local, state and federal programs that serve low-income communities rather than the Agency creating a new definition of "low-income community." Finally, the Agency recognizes the variability in state economic and demographic conditions, and the range of experiences that local, state and federal agencies have in administering low-income programs, including low-income energy programs. As a result, the EPA is proposing that it will neither create a new definition nor provide a single definition of low-income community that it will require states to use. Rather, the EPA proposes to provide states with the flexibility to use existing local, state or federal definitions that best suit their specific economic and demographic conditions while ensuring that eligible projects and programs receiving incentives are benefitting low-income communities. Local, state or federal definitions are considered existing if they were established prior to the publication of the final Clean Power Plan EGs on October 23, 2015. Routine updates of underlying federal or state data do not constitute a new definition for the purposes of this action.

It is reasonable to enable a state to include more than one definition of "low-income" in its state plan, to allow eligibility for a range of different types of programs (*e.g.,* housing vs. commercial) and geographic scale (*e.g.,* household vs. geographic boundary). Requiring a state to use only one could exclude projects that would be entirely consistent with the purposes of the Clean Power Plan EGs. There are many examples of existing federal definitions, including, but not limited to, geographic-based definitions, such as the New Market Tax Credits (NMTC) [69] and the HUD Qualified Census Tracts,[70] and household-based definitions, such as the Department of Energy's Weatherization Assistance Program (WAP) Income Guidelines [71] and the Federal Poverty Level Guidelines (FPLG).[72]

The EPA is proposing that these federal level definitions (NMTC, HUD Qualified Census Tracts, WAP, and the FPLG) are each presumptively approvable definitions that may be used in final state plans.[73] The EPA is requesting comment on other federal level definitions that could be included as presumptively approvable. At the state level, definitions may include established utility program definitions that have public utility commission (PUC) or state energy office (SEO) approval, eligibility requirements for state tax credits or incentives, or qualification for state administered benefit programs, among others. At the local level, definitions may include established utility program definitions administered by a municipality, a public power entity, a rural electric cooperative or other analogous utility provider not subject to state oversight. Examples of state and utility administered low-income EE and solar programs are discussed in section III.C of this preamble.

If a state includes more than one definition, it must have clear and consistent criteria for applying the multiple definitions. For instance, a state may use one definition for one type of program and another definition for another type of program, but it should not choose between the definitions for a specific program in such a way that would allow for arbitrary inclusion or exclusion of individual projects.

During the public outreach sessions on the CEIP in the fall of 2015, commenters raised concerns about the appropriateness of using state-based definitions. Specifically, some commenters stated that some state-specific definitions may either exclude some low-income electricity consumers or be overly inclusive of higher-income households or institutions that do not serve low-income residents. The EPA is requesting further comment on these concerns as well as potential remedies to address these concerns.

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[65] For more information about the link between minority and low-income communities please see Section V *Community and Environmental Justice Considerations.*

[66] Council on Environmental Quality's *Environmental Justice Guidance Under the National Environmental Policy Act, Appendix A* (December 1997). *http://www3.epa.gov/environmentaljustice/resources/policy/ej_guidance_nepa_ceq1297.pdf.*

[67] See the Final Clean Power EGs at section 60.5737(a)(4) and (b)(2) (80 FR 64943).

[68] See CEIP non-regulatory docket at EPA–HQ–OAR–2015–0734.

[69] *https://www.irs.gov/pub/irs-utl/atgnmtc.pdf.*

[70] *https://www.huduser.gov/portal/datasets/qct.html.*

[71] *http://energy.gov/eere/wipo/downloads/wpn-15-3-2015-poverty-income-guidelines-and-definition-income.*

[72] *https://aspe.hhs.gov/2015-poverty-guidelines.*

[73] See section III.C for information on requirements for eligible EE projects.

Additionally, some commenters have expressed concerns over needing appropriate safeguards to ensure that low-income communities are the beneficiaries of eligible CEIP energy-efficiency projects. Some commenters have suggested that states consider limiting the total population within a state that could be considered as 'low-income'. Others have suggested that states consider evaluating the number of high-income households that would be included under their proposed definition of low-income. Another commenter asked that states consider whether restrictions on the types of commercial and transmission and distribution projects are appropriate, (*e.g.,* whether the entities are public, private, or not-for-profit). In response to these concerns, the EPA is also requesting comment on restrictions or safeguards that may be needed to ensure that projects receiving incentives from the low-income community reserve are limited to those that benefit low-income communities.

The EPA requests comments on the suitability for a federal plan of the existing federal definitions listed previously (specifically: NMTC, HUD Qualified Census Tracts, WAP, and the FPLG), as well as any existing state or local definitions for programs in that state. This would be consistent with the flexibility granted to states under a state plan, as discussed previously.

As a state contemplates possible definitions of "low-income community" it may be appropriate to consider the range of factors specific to the state that impact the energy burden [74] on low income ratepayers (*e.g.,* disparities in median income across the state, utility prices, EJ concerns, or state median income in comparison with national median income). This can help states select a definition that maximizes inclusion of communities and households in which there are significant energy burdens and barriers to energy efficiency programs.

5. Requirements Addressing Potential Improper Allocation or Issuance of Early Action Allowances or ERCs

The EPA is proposing that state plans implementing the CEIP must include requirements for actions that will be taken if early action allowances or ERCs are improperly allocated or issued by the state.[75] Improper issuance by a state could occur as a result of error or misrepresentation by a CEIP-eligible resource. Because the EPA would also be awarding matching allowances or ERCs on the basis of state-issued early action allowances or ERCs, the EPA is proposing that the improper issuance provisions in a state plan that implements the CEIP must apply to both the state-issued early action allowances or ERCs and the corresponding EPA matching allowances or ERCs that are awarded.

The EPA is proposing that if a state or the EPA finds that any early action state allowances or ERCs have been improperly allocated or issued, then the EPA will bar award of matching allowances or ERCs to those projects that received improperly allocated or issued early action allowances or early action ERCs.[76] As described in section III.B of this preamble, in such an instance the EPA would place a hold on a state's matching allowance or ERC account, preventing the transfer of EPA matching allowances by the state from the EPA account to the account of the eligible CEIP resource at issue.

In the case where matching allowances or ERCs are awarded on the basis of improperly allocated or issued early action allowances or ERCs, the EPA is proposing that the EPA matching allowances or ERCs must be subject to requirements in a state plan that address improper allocation or issuance. The EPA has determined this approach is necessary because the EPA matching allowances or ERCs are compliance instruments that are indistinct from state-issued early action allowances or ERCs, and the award of the EPA matching instruments is predicated on the proper issuance of the state instruments. Both the state-issued compliance instrument and the EPA matching compliance instrument may be used by an affected EGU to comply with either a mass-based emission standard (allowances) or a rate-based emission standard (ERCs).

The EPA is proposing that state plans must include requirements specifying how improper allocation or issuance of early action allowances or ERCs will be addressed. The EPA is proposing that these plan requirements must apply to both state-allocated early action allowances and state-issued early action ERCs, as well as to the matching allowances or ERCs awarded by the EPA.

Where a state plan includes a rate-based emission trading program, the final Clean Power Plan EGs include requirements that a state plan must include provisions that address the improper issuance of ERCs.[77] The proposed rate-based model trading rule includes presumptively approvable provisions related to the improper issuance of ERCs.[78]

We propose that these finalized EGs provisions (which have already been promulgated and are not being reopened) and the corresponding proposed model rule provisions, are equally appropriate and would suffice for purposes of improper state issuance of early action ERCs under the CEIP.

Thus, the EPA is proposing that where a state implements the CEIP, those same provisions addressing state-issued early action ERCs in an approvable plan must also apply to any related EPA-awarded matching ERCs. Where any early action ERCs are found to be improperly issued by a state, the same requirements must apply to the matching EPA ERCs awarded on the basis of the original state-issued ERCs.

Where a state plan includes a mass-based emission budget trading program, the EPA is proposing to amend the final Clean Power Plan EGs to require that a state plan must include provisions like those in a rate-based plan under the EGs to address the improper state allocation of early-action allowances under a state CEIP. While mass-based plans under the EGs are required to include provisions for adjustment in the case of incorrect allocations, *see* 40 CFR 60.5815(d), the rules for improper issuance of ERCs under rate-based plans under the EGs are different. *See* 40 CFR 60.5790(c)(3); *id.* 60.5805(g), (h). Neither of these sets of requirements are being reopened. The EPA is proposing, however, that the rate-based approach would apply for purposes of the CEIP in both mass-based and rate-based state plans.

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[74] Energy burden is defined broadly as the burden placed on household incomes by the cost of energy, or more simply, the ratio of energy expenditures to household income. Nationally, the energy burden for households that qualified for federal low-income weatherization programs in 2014 was 16.3%, while the energy burden for non-eligible households was 3.5%. Expenditures on electricity represent a portion of the larger energy burden. *http://weatherization.ornl.gov/pdfs/ORNLTM2014_133.pdf.*

[75] This section uses the term "state-issued" to refer to both state allocation of early action allowances and state issuance of early action ERCs.

[76] The EPA award of matching allowances or ERCs is not considered EPA endorsement that such allowances or ERCs were properly allocated or issued in accordance with state plan requirements. Such allowances or ERCs are still subject to a potential subsequent finding that they were improperly allocated or issued, in accordance with the requirements in an approved state plan.

[77] See the EGs at 40 CFR 60.5790(c)(3); *id.* 60.5805(g) and (h). The potential for improper issuance of ERCs by a state is discussed in the preamble to the final EGs rule at section VIII.K.2.d (80 FR 64907, October 23, 2015).

[78] Provisions to address improper issuance of ERCs are discussed in the preamble to the proposed federal plan and model trading rules (80 FR 65000, October 23, 2015). See also, proposed rule text at 40 CFR 62.16450 of the rate-based model trading rule.

This is due to the availability of the matching allowances under the CEIP. State allocation of early action allowances under the CEIP is the necessary predicate for the award of EPA matching allowances, which would functionally expand the emission budget for affected EGUs under the state plan. These EPA matching allowances that are awarded to the state, if based on improper allocation by the state under its CEIP set aside, could potentially erode the integrity of a mass-based emission trading program under the Clean Power Plan.[79]

Because of the distinctions between the impact of state-allocated early action allowances and the award of EPA matching allowances described previously, the EPA is proposing an approach for mass-based state plans where a state plan must include provisions comparable to the improper issuance provisions for ERCs in a rate-based program that apply to the EPA matching allowances. A state plan could include different requirements that apply for the improperly state-allocated early action allowances under the CEIP. Under this proposed approach, application of the improper allocation provisions in an approved state plan would be triggered based on a finding by the state or the EPA that early action allowances were improperly allocated by the state under the CEIP. The remedies under the improper allocation provisions would address the EPA matching allowances, which resulted in a functional expansion of the state emission budget.

C. Requirements for CEIP-Eligible Projects

In the final EGs, we specified certain criteria for eligible projects, including the date after which eligible RE projects must "commence construction" and the date after which eligible EE projects must "commence operation." 40 CFR 60.5737. We requested comment in the proposed model trading rules and federal plan on what, if any, additional criteria should apply to determine eligibility for CEIP projects. 80 FR 65026. Accordingly, we are proposing to clarify the eligibility criteria for CEIP projects, guided by the objectives for the CEIP identified in the final Clean Power Plan, *see* 80 FR at 64829–64832, as well as the importance of ensuring simplicity in plan development and ease in implementation of this time-limited program.

We received significant input from a wide range of stakeholders about requirements for eligible CEIP projects. We considered this feedback carefully in developing this proposal. In this action, we propose to clarify the term "project" as used in the Clean Power Plan EGs for purposes of the CEIP. Additionally, in this action we propose to replace the definition of "commence construction" as applied to eligible RE projects, as well as to clarify the definition of "commence operations" as applied to eligible low-income EE projects. We are also proposing to remove the existing language from Section 60.5815, paragraph (c) of the Clean Power Plan EGs which pertained to EM&V requirements for the CEIP allowance set-aside, as duplicative, and we are clarifying and consolidating the EM&V requirements for eligible CEIP projects in this action.

1. Definition of "Project" for Purposes of the CEIP

The Clean Power Plan EGs specify that solar and wind, as well as low-income EE, "projects," are eligible for the award of early action allowances and ERCs under the CEIP.[80] The EPA is proposing to clarify that the current term "project" also encompasses programs that result in the deployment of CEIP-eligible solar, wind, geothermal or hydropower generating capacity and the implementation of CEIP-eligible EE or solar programs in low-income communities (*i.e.,* programs that deploy eligible projects). This clarification is simply to better reflect the EPA's intent and to maintain consistency with the approach in the Clean Power Plan EGs for issuance of ERCs, which refers to "eligible resources," a general term which encompasses both projects and programs.[81] The term "eligible resource" provides for the eligibility of both individual projects and programs for the issuance of ERCs, provided the project or program involves energy generation or savings from an eligible resource.[82] To clarify the term eligible project, the EPA proposes to add a new defined term, "eligible CEIP resource," to the final Clean Power Plan EGs (at 40 CFR 60.5880) and make related conforming amendments to the CEIP provisions in the EGs (at section 60.5737). In addition, as used throughout this preamble, the term "project" as it refers to projects eligible under the CEIP, also refers to programs that implement such projects. Consistent with the final emissions guidelines provisions for ERC issuance, an eligibility application submitted by a project provider under the CEIP may represent either an individual EE/RE project or multiple projects implemented as part of program (*i.e.,* it is not necessary for each project implemented as part of a larger program to submit its own eligibility application).

2. Definition of "Commence Construction" and "Commence Operations" for Purposes of the CEIP

In this action the EPA is proposing to replace the term "commence construction" for CEIP-eligible RE projects with the term "commence commercial operation," as well as to clarify the term "commence operations" for CEIP-eligible low-income community projects. The Agency believes that "commence commercial operation" is more consistent with the intent of the Clean Power Plan EGs. In addition, the Agency wishes to avoid any confusion with the term "commence construction" as used in other contexts under sections 111 and 112 of the CAA.

The Agency heard from several commenters during the CEIP outreach sessions and in comments submitted to the non-regulatory docket that "commence construction" could be understood to encompass such activities as entering into contracts for eligible RE projects. If this were the Agency's intent, according to these stakeholders, then the effect would be to render many RE projects ineligible as a result of early project development activities that may have occurred prior to the start date of eligibility. This was not the intent of the Agency, and we believe it is appropriate to correct this terminology to more accurately reflect the Agency's intent; that is, RE projects (including those in low-income communities) should be eligible to participate in the CEIP if they commence commercial operation on or after the eligibility start date. By replacing the term "commence construction" with "commence commercial operation," the EPA would be taking an approach to eligibility for RE projects that is consistent with the approaches that have been used in prior programs, such as the Acid Rain Program (ARP). In the ARP, the term "commence commercial operation" means "to have begun to generate electricity for sale, including the sale of test generation," *see, e.g.,* 40 CFR 72.2.

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[79] In the case of improperly allocated allowances, the allocation by the state would not be appropriately based on actual MWh of generation or savings from eligible resources under the CEIP, and related avoided CO_2 emissions prior to the beginning of the plan performance period. At the same time, the EPA matching allowances would expand the emission budget under the state emission budget trading program.

[80] See 40 CFR 60.5737(a) and (b).

[81] See definition of "eligible resource" at 40 CFR 60.5880.

[82] See the preamble to the final Clean Power Plan EGs, at section VIII.K.2.b (80 FR 64906–64907) and section VIII.K.2.f (80 FR 64907), and the EGs at 40 CFR 60.5800(a).

With respect to the term "commence operations" for CEIP-eligible demand-side EE projects implemented in low-income communities, the EPA is proposing to establish a definition that is consistent with the proposed replacement of "commence construction" with "commence commercial operation" discussed previously. That is, the EPA is proposing that the term "commence operations" be defined as the date that a CEIP-eligible low-income community demand-side EE project is delivering quantifiable and verifiable electricity savings.[83] This means the date when the eligible CEIP low-income community demand-side EE project's electricity savings begin and are measureable is the date when the project commenced operation for the purpose of CEIP eligibility. Additionally, the term "commercial" is excluded from the "commence operations" term used for eligible EE projects implemented in low-income communities, as "commercial" is used as a qualifier to describe when electricity is available for sale or to generate electricity that receives financial credit through net metering or equivalent policies (as in the case of power generation), not when it is saved (as in the case of EE projects).

In light of the proposed corrected terminology from "commenced construction" to "commenced commercial operations", the EPA is proposing to revise the date for eligible CEIP RE projects (including those implemented in low-income communities) to commence commercial operation to January 1, 2020, or commence operations, in the case of low-income demand-side EE projects, to September 6, 2018. First, the proposal to no longer use the date of final state plan submittal as a potential eligibility start-date would remove a source of uncertainty given the Supreme Court's stay of the Clean Power Plan EGs in *West Virginia, et al.* v. *EPA, et al.,* No. 15A773 (February 9, 2016). Because the effectiveness of deadlines for state plan submittals is currently stayed, it may not make sense at this point to continue to tie CEIP project eligibility to plan submissions. However, as discussed previously, while we are retaining the putative timing aspects of the CEIP in general in discussing this proposal, the Agency recognizes that adjustments may be needed upon the resolution of the litigation. *See* discussion in section II.B of this preamble.

Second, in the case of RE projects looking to become eligible CEIP projects, the date of January 1, 2020 for eligibility for projects that have commenced commercial operations reflects the initial intent of the timing finalized in the Clean Power Plan EGs. The previous language that based eligibility timing on when a project "commenced construction" considered the build-out time that would be required from the time of a project's initial conception. Since the CEIP is designed primarily to encourage additional renewable deployment, establishing a date of January 1, 2020 supports the overarching goal of the CEIP to encourage such deployment.

For eligible CEIP low-income community demand-side EE projects, some commenters have requested that the EPA should allow an expanded ramp-up period for projects. Commenters stated that while energy efficiency programs can be deployed quickly, adequate ramp-up time must be allowed to thoughtfully design and target programs, and to achieve desired levels of volume. The EPA agrees with this comment, and the additional time needed for adequate design and targeting of eligible CEIP low-income community demand-side EE projects is reflected in the eligibility date of September 6, 2018. Additionally, we agree with commenters' assertions that eligible CEIP low-income community demand-side EE projects need ramp-up time to ensure that they realize the full benefits of the CEIP following project deployment.

Given that the CEIP project eligibility approach included in the final Clean Power Plan EGs was tied to commencement of construction after submission of a state plan, and that there may be additional relevant factors not considered here, EPA seeks comment on whether the proposed approach described above, the approach included in the final Clean Power Plan EGs, or a combination of the two approaches, would best serve the goals of the CEIP.

3. Option to use an Agent for reviewing CEIP project applications, allocating early action allowances, and issuing early action ERCs. As discussed in section III.B of this preamble, a state plan that implements the CEIP must specify a process for application, and allocation/issuance of, early action allowances or ERCs under the CEIP to eligible project providers. The proposed rate- and mass-based model trading rules include related provisions that, when finalized, would constitute a presumptively approvable approach for meeting relevant EGs requirements (80 FR 64966–65116), and the EPA is proposing optional example provisions in this action to cross-reference those provisions under the CEIP.

This process, defined by the state in its plan requirements, may be implemented by the state itself, or alternatively the state may delegate this function to a qualified agent. The ability to rely on agents is discussed further in the final Clean Power Plan EGs at 80 FR 64906.[84] The EPA is not proposing any specific requirements with respect to the use of agents in this action, nor reopening the issue of a state's ability to rely on agents under the EGs. We simply observe here that the use of agents would also be appropriate under the CEIP for similar purposes.

In the event of a federal plan, the EPA anticipates that it would serve the same role as the state, and thus the EPA, or an agent(s) it may designate, would review project applications and reports of quantified and verified MWh in advance of allocating early action and matching allowances, and issuing early action and matching ERCs to eligible project providers.

4. Eligible CEIP RE projects. In 40 CFR 60.5737 of the final EGs, the EPA established that eligible CEIP RE project types are those that "generate metered MWh from any type of wind or solar resources." In order to streamline the requirements for eligible CEIP wind and solar resources, as well as to clarify the requirements for geothermal and

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[83] For infrastructure projects such as conservation voltage reduction (CVR) that deliver end-use energy efficiency in residences and buildings, it is common practice to test circuit performance by switching voltage optimization controls "on" and "off" for a continuous period of time (typically a year) to collect baseline data for quantification of savings during the performance period. Similar to the Agency's intent that wind and solar projects not be penalized for project development activities that occur prior to commencing commercial operations, voltage management of a circuit solely for the purpose of testing prior to "commencing operations" does not render a circuit ineligible for participation in the CEIP. Similarly, a limited duration or one-time control of voltage during a peak demand incident does not render a circuit ineligible for participation in the CEIP.

[84] As described in the Clean Power Plan EGs, an agent is a party acting on behalf of the state, based on authority vested in it by the state, pursuant to the legal authority of the state. A state could designate an agent to provide certain limited administrative services, or could choose to vest an agent with greater authority. Where an agent issues an ERC on behalf of the state, such issuance would have the same legal effect as issuance of an ERC by the state. In the context of the CEIP, such an agent may also be vested with the authority to issue allowances. Where an agent issues an allowance on behalf of the state, such issuance would have the same legal effect as issuance of an allowance by the state.

hydropower resources we are proposing to add to the list of CEIP-eligible resources, the EPA is proposing in this rule to change the project eligibility requirements so that eligible CEIP RE projects must generate wind, solar, geothermal or hydropower renewable electricity measured in MWh consistent with the requirements of 60.5830(c)(1) of the final CPP EGs: The generation data must be physically measured on a continuous basis. These RE resources may include utility-scale or distributed projects, and must be grid-connected. In the case of solar power generation, solar resources could be solar photovoltaic or concentrating solar power technologies.

The limitation of eligible CEIP RE technologies to wind and solar in the Clean Power Plan EGs was based partially on the concern from commenters on the Clean Power Plan proposal that there could be an unintended shift in investment away from RE to natural gas, and partially on the fact that these technologies—in addition to being essential for longer-term climate strategies—generally can be deployed with shorter lead times than other technologies (*See* 80 FR 64831). Therefore, wind and solar would be readily available for participation during the two-year CEIP period. However, the extension of the PTC and ITC tax credits following the promulgation of the Clean Power Plan EGs has led some stakeholders to suggest that wind and solar projects that receive PTC or ITC benefits should be excluded from CEIP eligibility. This is because one of the objectives of the CEIP is to incentivize reductions in emissions that might not otherwise have occurred, and projects receiving tax credits may already be induced by those incentives rather than the CEIP. These tax credits are discussed more fully in section III.A of this preamble, where we also request comment on whether and how to implement limitations on CEIP participation for wind and solar resources that receive ITC or PTC benefits.

In addition, stakeholders have noted that other types of clean generating technologies, in addition to wind and solar, could be deployed during the CEIP timeframe,[85] and therefore, should also be included as eligible for the CEIP. Specifically, some commenters requested that the EPA consider other renewables such as geothermal and hydropower. Other stakeholders have called for all of the technologies the EPA recognized as potentially creditable in state plans under the final EGs, including qualified biomass, CHP, WHP, and nuclear projects, to be CEIP creditable. The Agency also received several petitions for reconsideration on the final Clean Power Plan requesting that the scope of CEIP technology eligibility be expanded.[86]

The EPA believes that our initial determination of criteria for eligible technologies remains appropriate, and, therefore, are retaining those criteria. The criteria we identified in the final Clean Power Plan that drove our determination of eligible technology types for the CEIP were that they are zero-emitting and essential to longer term climate strategies, and require lead times of relatively shorter duration given the time-limited nature of the CEIP and to counteract the potential shift in investment from RE to natural gas in the lead up to the start of the interim performance period. See 80 FR 64831.

As noted in section II.D. of this preamble, some commenters requested that other RE technologies, including geothermal, biomass, hydropower, as well as other generating technologies such as combined heat and power (CHP) and waste heat to power (WHP) be considered as eligible technologies for the CEIP. While we do not believe that it is appropriate to expand the list of eligible CEIP technologies to include all those suggested by commenters, we believe that two other RE technologies, specifically geothermal and hydropower, meet the criteria for CEIP eligibility that were identified in the final CPP. Thus, in this action we are proposing to expand the list of CEIP-eligible RE technologies beyond wind and solar resources alone only to two other zero-emitting technologies: Geothermal and hydropower.[87] The EPA believes stakeholders are correct that these two technologies, like wind and solar, are capable of contributing to long-term climate change strategies, and can be implemented on the time-scales relevant to the CEIP. *See* 80 FR 64831. Expected growth in these technologies may be lower than wind and solar, 80 FR at 64808, but this would not be a reason for excluding them. Any scale or type of wind and solar project, as finalized in the EGs, would remain eligible for the CEIP, assuming other eligibility requirements are met.[88] The EPA is only proposing the expansion of eligible CEIP RE projects to include geothermal and hydropower. We solicit comment on whether any additional technologies meet the criteria identified for eligible RE technologies: Specifically, whether there are additional renewable technologies that are zero-emitting and essential to longer term climate strategies, require investment and deployment lead times of relatively shorter duration given the time-limited nature of the CEIP, and counteract the potential shift in investment from RE to natural gas in the lead up to the start of the interim performance period.

5. Eligible CEIP low-income community projects. The Clean Power Plan EGs established that demand-side energy efficiency projects implemented in low-income communities would be eligible for the two-to-one CEIP incentive. This section discusses eligible low-income EE projects, and also presents a proposal that solar projects implemented to serve low-income communities that provide direct electricity bill benefits to low-income ratepayers also be eligible for the two-to-one incentive.

Demand-side energy efficiency refers to an extensive array of technologies, practices and measures that are applied throughout all sectors of the economy to reduce electricity demand while providing the same, and sometimes better, level and quality of service.[89] The EPA is proposing that states have flexibility to determine the types of demand-side EE projects they may deem eligible for CEIP awards, so long as they are implemented in communities that meet the state's approved definition(s) for "low-income community." Such projects may be implemented as part of an EE program (*i.e.*, implemented by regulated electric distribution utilities or other private providers), which could play a key role in generating early action ERCs or allowances. Specifically, states may deem residential and commercial projects to be eligible for CEIP awards, as well as transmission and distribution improvements that reduce electricity consumption on the customer side of the meter (such as conservation voltage reduction). The EPA notes that in some instances multi-family housing, group homes, shelters or other temporary housing may be considered commercial entities for utility billing purposes. Excluding these commercial entities from CEIP could keep these residential ratepayers from being eligible under CEIP. Additionally, our experience has been that small businesses, organizations and institutions that work with low-income residents often face similar energy risks (*e.g.*, large bills, disproportionate energy spending, shutoff threats) and experience the same barriers (*e.g.*, lack of capital, lack of expertise, split incentives for renters) as the residential sector. High energy expenses hamper their ability to provide clients with energy, health, educational, housing, legal and other services. Thus, the EPA believes all of these types of EE projects can be designed to benefit low-income communities and ratepayers, and all have the potential to encourage investment in demand-side energy efficiency projects (in part by offsetting the higher barriers to deployment for such projects in those communities), for the purpose of achieving emissions reductions at affected EGUs, in accordance with the purposes of the CEIP, 80 FR 64832. For residential projects, the EPA recommends that the state consider projects that adhere to the health and safety standards established by the Department of Energy's Weatherization Assistance Program or comparable standards. For commercial EE projects, the EPA recommends that a state consider projects that reduce electricity demand in buildings and institutions that provide critical services (*e.g.*, community centers, street lighting, health clinics, etc.) within or to low-income communities and/or households. For transmission and distribution improvement projects that reduce energy consumption on the customer side of the meter, the EPA recommends that a state consider improvements that significantly reduce consumer electricity demand within the boundaries of a low-income community or within low-income households. EPA requests comment on the inclusion of commercial and transmission and distribution projects, and on whether there should be any restrictions on the types of commercial and/or transmission and distribution projects that may qualify.

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[85] See document titled "Summary of feedback received during the CEIP listening sessions, Fall 2015" in the docket associated with this action, as well as the CEIP non-regulatory docket at EPA–HQ–OAR–2015–0734.

[86] While there is some overlap in this action on this and several other issues relating to the CEIP raised by the petitions for reconsideration, the Agency continues to review, and is not acting on, these or any other aspects of the petitions for reconsideration of the Clean Power Plan at this time.

[87] *See* 80 FR 64807 and also the TSD to the final Clean Power Plan titled "GHG Mitigation Measures."

[88] "Any type" of wind or solar resource is already eligible under the CEIP as finalized in the EGs, 80 FR at 64943, and the EPA is not reopening this determination.

[89] A number of demand-side EE measures are discussed in the TSD to the Clean Power Plan Final Rule titled "Demand-Side Energy Efficiency," August 2015, available at *https://www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-technical-documents*. Typical examples of energy efficiency measures in homes include: Air and duct sealing, increased insulation in walls and attics, highly efficient equipment for heating and air conditioning (*e.g.*, air- and ground-source heat pumps, high efficiency furnaces, etc.), and highly efficient appliances (*e.g.*, refrigerators, television sets, etc.).

The Department of Energy, in cooperation with industry, has developed a suite of quality assurance resources that address work quality, training and workforce certification. The EPA has also developed resources to assist program managers with implementing residential and commercial energy efficiency programs under the auspices of the ENERGY STAR program as well as resources that address indoor air quality and energy efficiency. These resources are applicable to all energy efficiency retrofit programs, including low-income, regardless of design, administration or scope. States are encouraged to consider use of DOE's *Guidelines for Home Energy Professionals*[90] and DOE's *Better Buildings Workforce Guidelines*[91] as well as EPA's *Guidance and Tools for Protecting IAQ During Building Upgrades*,[92] and ENERGY STAR's resources for residential and commercial energy efficiency.[93]

A number of states have already implemented successful low-income EE projects and programs that can serve as examples to other states as they consider the project types that may be possible through the CEIP. We present examples of two of these projects in section III.C of this preamble.

The EPA is proposing to include solar projects implemented to serve low-income communities that provide direct electricity bill benefits to low-income community ratepayers as eligible for the two-to-one matching award from the reserve established for low-income EE projects. This would be a change from the CEIP provisions included in the Clean Power Plan EGs, which limited projects eligible for the two-to-one match to low-income EE projects alone. However, during the outreach sessions in the fall of 2015, stakeholders suggested solar projects in low-income communities face many of the same barriers to deployment as do EE projects, and provide the same environmental benefit in terms of displacing carbon-emitting generation. Based on such input from stakeholders and other information, the EPA believes that solar technology—particularly distributed, rooftop, or community solar—is particularly well suited among zero-emitting RE resources to implementation in low-income communities, as it is relatively affordable compared to other distributed RE technologies, it is already widely available for installation, and the primary barriers to deployment are economic rather than technical. Enabling such projects to receive the two-to-one match would serve the same basic purpose of improving cost impacts and expanding compliance opportunities for affected EGUs under the Clean Power Plan. In addition, as discussed in section III.A of this preamble, the EPA's preliminary analysis shows that the MWh savings potential for eligible low-income EE projects is relatively low even with the CEIP as a driver, and as a result it may be appropriate to enable equally beneficial solar projects implemented in low-income communities to be eligible for awards from the matching allowance/ERC reserve for low-income community projects.

By including such provisions in the CEIP, any type of solar project implemented to serve a low-income community that provides direct electricity bill benefits to low-income community ratepayers would be eligible for a two-to-one award from the low-income community reserve of the matching pool.

Some of the types of solar projects that the EPA envisions could qualify for awards from the low-income community reserve include roof-top solar and community-owned solar projects.[94] A number of states have already implemented successful solar projects that can serve as examples to other states as they consider the project types that may be possible through the CEIP. We present an example of one of these projects in section III.C of this preamble.

The EPA solicits comment on the types of solar technologies and programs that could be eligible for the low-income community reserve of the matching pool, and how states may be able to determine benefits delivered to low-income community ratepayers. We also solicit comment on whether wind generation, geothermal, or hydropower may provide similar ratepayer benefits to low-income communities. The intent of the low-income community reserve in the matching pool is to make awards available to projects that provide direct electricity bill benefits to low-income ratepayers, and the EPA's objective is to ensure that any program that has access to this pool fulfills this criterion.

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[90] *http://energy.gov/eere/wipo/guidelines-home-energy-professionals.*

[91] *https://www4.eere.energy.gov/workforce/projects/workforceguidelines.*

[92] *https://www.epa.gov/indoor-air-quality-iaq/health-energy-efficiency-and-climate-change.*

[93] *https://www.energystar.gov/.*

[94] The following links provide examples of several existing programs: *http://solar.gwu.edu/research/bridging-solar-income-gap; http://www.cesa.org/assets/2014-Files/Clean-Energy-for-Resilient-Communities-Report-Feb2014.pdf. https://www.solarelectricpower.org/media/422095/community-solar-design-plan_web.pdf.*

a. Examples of EE and RE projects implemented in low-income communities. This section presents three examples of low-income EE and RE programs currently underway in states around the country: Energy Outreach Colorado (EOC), the PECO Conservation Voltage Reduction Program, and the Multifamily Affordable Solar Housing (MASH) Program in California. These examples may be of assistance to states exploring the development of EE and RE programs in low-income communities.[95]

The first example is EOC, an independent non-profit organization that works to ensure all Coloradans can meet their home energy needs through emergency bill payment and furnace repair assistance, energy efficiency improvements, consumer behavior change and advocacy for the energy needs of low-income households.[96] EOC's Affordable Housing Weatherization Program serves affordable multi-family housing properties across the state that have five or more units, are centrally heated, and where 67 percent of the residents are at or below 200 percent of the federal poverty level. EOC also developed the Nonprofit Energy Efficiency Program, which offers facility energy efficiency grants to non-profit organizations serving low-income individuals and families. The program helps nonprofit organizations reduce energy expenses in their own commercial buildings so that they can allocate more of their operating budgets to community services. Since its creation in 1989, EOC has saved low-income utility customers 19,200 MWh of electricity, thereby reducing or avoiding almost 16,000 metric tons of CO_2 emissions.[97]

The second example is the PECO Conservation Voltage Reduction (CVR) program, a program implemented in the state of Pennsylvania to achieve load reductions through changes in voltage regulation parameters at the substation/transformer level.[98] National standards for voltage generally require electricity to be delivered to consumers between 114 and 126 Volts. Due to transmission line losses, power is transmitted at the higher end of that range to ensure all customers receive the minimum voltage. However, many homes receive more voltage than they need, resulting in higher energy use and higher bills. By adjusting voltage to the lower end of its acceptable range, customers save energy because some equipment operates more efficiently at lower voltage. Since the efficiency opportunity is implemented by the utility, all customers on the affected feeders benefit with no need for household level action. During a 4-month period from February through May 2010, PECO manually lowered voltage by one percent across its system (involving approximately 84 substations, 220 distribution transformers, and 6400 circuits). Reported gross energy savings were 25,630 MWh/yr for low-income customers and 38,445 MWh/year for government and non-profit customers, resulting in reductions of approximately 45,000 metric tons of CO_2.[99]

The last example is the Multifamily Affordable Solar Housing (MASH) Program, overseen by the California Public Utilities Commission. This program has brought solar energy to thousands of multifamily building owners and tenants across the state. MASH offers an up-front rebate to offset the costs of new solar energy systems for qualified, existing multifamily low-income housing. The program uses "virtual net metering" to allow the tenants to benefit from lower electricity bills due to the energy generated by the solar energy system. From 2008 to 2015, MASH has led to the installation of more than 23 MW of solar capacity across nearly 360 projects[100] serving more than 6,500 low-income households.[101] In buildings that have implemented virtual net metering, tenants' electricity bills have fallen by an average of about $480 over the first year. According to a third-party evaluation of the program, the MASH solar energy systems avoided more than 27,450 tons of CO_2 emissions from 2011 to 2013.[102]

D. CEIP Participation for States, Tribes, and Territories for Which the EPA Has Not Established Goals

1. Participation for Tribes Without Affected EGUs

Many tribes have expressed interest in participating in the CEIP even though they do not have EGUs subject to the Clean Power Plan EGs. These tribes have the potential to develop RE and low-income community projects that could qualify as eligible CEIP projects. As finalized in the EGs, such projects would in general be able to apply and receive early action allowances or early action ERCs through state plans that include the CEIP. However, several tribes have expressed concern that requiring tribes to participate in the CEIP by applying for early action ERCs or allowances from CEIP-participating states would infringe upon their sovereign rights. In addition, some stakeholders have expressed concern that without explicit direction to deploy projects on tribal lands, project providers will opt to invest in CEIP-eligible projects only on the lands of CEIP-participating states, and not on tribal lands. Lastly, tribes have also expressed concern that in order to remain competitive in wind and solar deployment, they must consider CEIP participation as part of their strategy.

The EPA does not agree that the CEIP would result in an infringement on tribal sovereignty, because neither the Clean Power Plan nor the CEIP impose legal obligations on tribes without affected EGUs or authorize states to impose such obligations. Rather, the Clean Power Plan and the CEIP provide opportunities for projects located on tribal lands to voluntarily seek credit through a state plan that regulates affected EGUs. Further, the EPA wishes to clarify that an eligible project that is located in Indian country within the borders of a state, solely for the purposes of the CEIP, is considered to be "located" in the state, in order to facilitate such projects' eligibility to voluntarily seek early action allowances or early action ERCs under the CEIP. In other words, the EPA does not require that a project fulfill a "benefit" demonstration in addition to meeting the grid-connection requirement, solely because it is located in Indian country.[103] The fact that projects located in Indian country may voluntarily seek crediting under a state plan does not constitute an approval of a state plan as applied in Indian country. The plan of a surrounding state merely provides an opportunity for projects located in Indian country to voluntarily participate in the CEIP by applying to such state for credits. This clarification may address some concerns about the ability of projects located in Indian country to be eligible for the CEIP.

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[95] These examples are illustrative only. More information on these examples is available on the EPA Web page titled "Climate and Energy Resources for State, Local and Tribal Governments" at *https://www.epa.gov/statelocalclimate/bringing-benefits-energy-efficiency-and-renewable-energy-low-income-communities*. Although we believe these programs are successful and worthy of replication, the EPA has not determined if they would qualify for awards under the CEIP.

[96] See *http://www.energyoutreach.org/*.

[97] MWh savings data are from personal communications with Jennifer Gremmert, Energy Outreach Colorado, January 2016. CO_2 savings were calculated using the 2012 eGRID non-baseload CO_2 emissions rate for the WECC Rockies subregion (1822.65 lbs CO_2/MWh). See EPA's Emissions & Generation Resource Integrated Database (eGRID) at *https://www.epa.gov/sites/production/files/2015–10/documents/egrid2012_summarytables_0.pdf*, Table 3.

[98] Source: Final Annual Report to the Pennsylvania Public Utility Commission for the Period June 2011 through May 2012, Program Year 3, For Pennsylvania Act 129 of 2008 Energy Efficiency and Conservation Plan, Prepared by Navigant Consulting, Inc. for PECO, November 15, 2012.

[99] MWh savings data are from the Final Annual Report to the Pennsylvania Public Utility Commission for the Period June 2011 through May 2012, Program Year 3, For Pennsylvania Act 129 of 2008 Energy Efficiency and Conservation Plan, Prepared by Navigant Consulting, Inc. for PECO, November 15, 2012. *https://www.peco.com/CustomerService/RatesandPricing/RateInformation/Documents/PDF/New%20Filings/ACT%20129%20EECP.pdf*. CO_2 savings were calculated using the 2010 eGRID non-baseload CO_2 emissions rate for the RFC East subregion (1562.72 lbs CO/MWh). See EPA's Emissions & Generation Resource Integrated Database (eGRID) at *https://www.epa.gov/sites/production/files/2015-01/documents/egrid_9th_edition_v1-0_year_2010_summary_tables.pdf*, Table 3.

[100] California Solar Statistics. Application status page, MASH program. *https://www.californiasolarstatistics.ca.gov/reports/application_status/?source=mash*.

[101] California Public Utilities Commission, 2015. Multifamily Affordable Solar Housing Semiannual Progress Report, July 31, 2015. *http://www.cpuc.ca.gov/General.aspx?id=3752*.

[102] Navigant, 2015. California Solar Initiative—Biennial Evaluation Studies for the Single-Family Affordable Solar Homes (SASH) and Multifamily Affordable Solar Housing (MASH) Low-Income Programs Impact and Cost-Benefit Analysis Program Years 2011–2013. Prepared for California Public Utilities Commission.

Nonetheless, the EPA invites comment on an approach that may further enhance the ability of project providers located in Indian country without affected EGUs to participate in the CEIP. The approach for which we seek comment would be to include as a condition of participation in the CEIP a requirement that state plans may not disqualify an otherwise eligible CEIP project on the basis that it is located in Indian country or in any way apply different requirements to applications for CEIP projects located in Indian country. This approach would provide tribes and project developers in Indian country with assurance that their projects will be given the same consideration as all other projects that are located in or benefit a CEIP-participating state. In such a scenario, a project in Indian country would be eligible for an early action award from the state, and the complementary matching award from the EPA.

The EPA also invites comment on other possible approaches that may enable CEIP-eligible projects located in Indian country to participate in the CEIP.

2. Participation for Non-Contiguous States and Territories

As stated in the final Clean Power Plan, the EPA did not finalize emission guidelines for the fossil-fuel fired EGUs in Alaska, Hawaii, Guam or Puerto Rico because of the lack of suitable data and analytic tools needed to develop area-appropriate building block targets (*See* 80 FR 64825; October 23, 2015). The EPA is still in the process of assessing the achievability of emissions reductions for the affected EGUs in these remaining jurisdictions and thus has not taken further action to finalize emission guidelines for them.

The EPA acknowledges that project providers that may be located in non-contiguous states and territories are interested in the opportunity to participate in the CEIP. The Agency recognizes that these projects should have opportunities and access to the same early action incentives as the contiguous states. However, the Agency believes such opportunities can only be available at the point that emissions guidelines are put in place for these jurisdictions. Projects in these non-contiguous jurisdictions are not connected to the contiguous U.S. electrical grid and cannot be said to be located in or benefit a CEIP state, and are thus ineligible to generate either ERCs or early action ERCs or early action allowances under the final Rule and this proposal. 40 CFR 60.5800(a)(2). *See also id.* 60.5737 (both as finalized and as proposed to be amended by this action, requiring CEIP projects to be located in or benefit the state operating the CEIP program).

Nonetheless, the EPA anticipates making available CEIP participation for these remaining states and territories when the Agency finalizes emission guidelines for fossil-fuel fired EGUs in these states and territories. The EPA anticipates that matching allowances or ERCs for noncontiguous states and territories would be apportioned from the existing matching pool of 300 million short tons of CO_2 emissions. Therefore, as noted in section III.A of this preamble, the total amount of CEIP matching allowances or ERCs apportioned among the rest of the states would be reduced accordingly, albeit only by a small percentage, likely no more than 5 percent.

The EPA is taking comment on how to determine the appropriate portion of the matching pool that should be apportioned to the non-contiguous states and territories, if they choose to participate in the CEIP. The EPA could attempt to estimate the pro rata share of the matching pool for each of the non-contiguous states and territories with affected EGUs before the emission performance goals have been finalized for these jurisdictions. The Agency requests comment on approaches that could be used to estimate the appropriate share for these locations while their goals are still undetermined. Alternatively, the EPA could defer apportioning the matching allowances or ERCs to these states and territories until such time when their emission performance goals are established. At that future time, the matching shares would be calculated by applying the methodology described in this action and the matching shares apportioned to the contiguous states would be adjusted. The EPA is soliciting comments on both of these approaches.

3. Participation for States Without Affected EGUs

For the contiguous U.S. states, the EPA is providing the opportunity for participation in the CEIP only for those states with approved state plans and those states that may become subject to a federal plan. Since states without affected EGUs do not have an obligation to submit a state plan for EPA approval under CAA section 111(d), there is no clear path for inclusion of these states in the CEIP.

However, eligible projects developed in those states without affected EGUs may apply for and receive early action allowances or ERCs from another state that has chosen to participate in the CEIP. The developers of such eligible RE and low-income community projects may receive early action allowances or ERCs from another state, so long as the project benefits the state providing the award and that state has an approved final plan establishing its participation in the CEIP. The final EGs recognized the potential CEIP eligibility of projects that "benefit" a state even if they are not located in that state. 80 FR 64830. In the Clean Power Plan, however, we did not explain what "benefit" means in the context of the CEIP. For purposes of the CEIP, we propose that "benefit" a state means that the electricity is generated or saved with the intention to meet or reduce electricity demand in the CEIP participating State.

This approach is intended to parallel the approach to providing ERCs to RE projects that are located in a mass-based plan state for use in compliance under a rate-based plan. 40 CFR 60.5800(a)(3)(ii). A project could meet this test by submitting documentation such as a power purchase agreement, see 80 FR 64913.

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[103] Where a project provider in Indian country seeks to apply for early action allowances or early action ERCs under the CEIP in a state other than the one in which that Indian country is located, then that project would need to meet the "benefit" test, in the same way that a project located in a different state from the one it is applying to would need to meet that test.

IV. Community and Environmental Justice Considerations

As discussed in the Clean Power Plan EGs, the additional incentive offered for low-income community projects by the CEIP, in addition to supporting affected EGU compliance and reducing costs by rewarding emission reduction measures that occur earlier than the performance period under the EGs, will help overcome historic barriers to the deployment of energy efficiency and solar projects in low-income communities. Bringing these energy efficiency and solar projects to low-income communities can also provide low-income ratepayer benefits (80 FR 64831).

In response to stakeholder concerns during the outreach session that the program does not explicitly direct its benefits towards EJ communities, the EPA examined the characteristics of different communities that may benefit from the CEIP, and our analysis demonstrates that by making EE projects in low-income communities eligible for the CEIP, the projects can also provide benefits to other underserved populations, including minority communities. A complete discussion of the methodology and results reported in this section is available in the TSD to this action titled "Community and Environmental Justice Considerations".

We performed two analyses to look at how minority populations could be assisted by energy efficiency projects or programs that may be located in low-income populations.[104] Both analyses use data collected by the U.S. Census Bureau.

For the first analysis we examined, on a national level, the relationship between low-income and minority populations. Income and race data are drawn from the U.S. Census Bureau's Report, Income and Poverty in the United States: 2014.[105] For the purpose of this analysis, we define low-income individuals as having family income less than twice the federal poverty level, and we define minority as all racial categories identified in the report except "White, not Hispanic." Using these definitions, in 2014, 33 percent of the U.S. population was low-income while 38 percent was minority. However, in the U.S., approximately half (47 percent), of those individuals who identify as minority are also low-income.

While the first analysis focused on the overlap between income and race at the national-level, we also investigated the geographic overlap between low-income and minority populations, because, as noted in section III.B of this preamble, the EPA expects that both household-based definitions and geographically-based definitions may be used to identify eligible projects in "low-income communities". The second analysis compares demographic data by Census block group using the 2008–2012 American Community Survey (ACS) five-year summary file, available through EPA's EJSCREEN tool.[106] The block group is a geographic unit used by the U.S. Census Bureau and is generally defined to contain between 600 and 3,000 people. For this analysis, a low-income household is one with an income less than two times the federal poverty level, while the term "minority" includes individuals who identify themselves as one of any racial categories except "White, not Hispanic." For this second analysis, we used two approaches for defining a low-income and minority block group. The first approach defines low-income and minority block groups based on how they compare to national shares of the population in these categories, while the second approach defines these relative to state shares of the population in these categories. Nationally, in 2014, 33 percent of the population are low-income while 38 percent are minority; if the percentage of the population in a block group exceeded the national percentage of the population that is low-income or minority, it was considered low-income or minority respectively. If a block group exceeded both these percentages, then we classified that block group as both low-income and minority. We found that, using these national percentages, 70 percent of minority block groups are also low-income.

In the second approach, for each state, we used the pre-calculated means for low-income and minority populations in that state, available in the EJSCREEN data files. We compared the share of the population that is low-income or minority in each block group to that state's mean. If a block group exceeded the state mean for low-income or minority, then it was considered low-income or minority, respectively. We found that 70 percent of minority block groups are also low-income, which is the same as was found using the national percentages.

These analyses support a conclusion that providing fully one half of the CEIP incentives to the low-income community reserve will provide additional benefits to EJ communities, and will be an important tool to bring the public health and economic advantages of clean energy to traditionally overburdened communities. We welcome comments on this analysis and the elements of the CEIP from this perspective.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. This action raises novel legal or policy issues. As noted earlier, the EPA took final action in the Clean Power Plan to establish the framework for the CEIP, while identifying other design details that it would address in a future action. For example, in the final Clean Power Plan, the Agency established the CEIP framework, including the overall size of the matching pool available to CEIP-participating states and the matching award the EPA will make to qualifying RE and low-income community projects per MWh of electricity generation or savings.

This action proposes design details of the CEIP that are consistent with the framework established in the final Clean Power Plan. Given that the framework of the CEIP has already been established in the Clean Power Plan EGs, the design details proposed in this action are not expected to result in significant costs, benefits, or economic impacts, beyond those associated with the Clean Power Plan EGs.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing part 75 and 98 regulations (40 CFR part 75 and 40 CFR part 98) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control numbers 2060–0626 and 2060–0629, respectively. There are no additional recordkeeping and reporting activities for this action that occur during the current reporting period covered by the existing ICR.

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[104] As discussed in section III.B of this preamble, a state that chooses to participate in the CEIP must include in its state plan one or more definitions of low-income community. In the analysis described in this section, the income level that defines a low-income household or community is illustrative, in order to demonstrate the correlation between low-income households and EJ communities. The use of this income level for this analysis is not intended to limit a state's definition of a low-income household or community for the purposes of implementing the CEIP. In addition to being the income level used in EJSCREEN to identify a low-income household, it is also the definition of poverty used in the U.S. Census Bureau's *Income and Poverty in the United States* report that includes the largest share of the U.S. population.

[105] DeNavas-Walt, Carmen and Bernadette D. Proctor, U.S. Census Bureau, Current Population Reports, P60–252, Income and Poverty in the United States: 2014, U.S. Government Printing Office, Washington, DC, 2015.

[106] EJSCREEN, *http://www.epa.gov/ejscreen.*

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. As previously discussed, the CEIP is an optional program that offers incentives for voluntary early actions involving RE and low-income energy efficiency. This action will not impose any requirements on small entities. Instead, this action proposes requirements that would need to be met by states in the event that states voluntarily opt into the CEIP under the Clean Power Plan. In the event of a federal plan, EPA continues to intend that it would implement the CEIP directly. Even where a state chooses to participate in the CEIP, small entities would not be subject to requirements except to the extent that they wish to voluntarily apply to receive early action ERCs or allowances, in which case certain conditions would apply.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The costs involved in this action are imposed only by voluntary participation in an optional program. UMRA generally excludes from the definition of "federal intergovernmental mandate" duties that arise from participation in a voluntary federal program.

E. Executive Order 13132: Federalism

This proposed rule does not have federalism implications. The EPA believes, however, that this proposed rule may be of significant interest to state and local governments. Consistent with the EPA's policy to promote communications between the EPA and state and local governments, the EPA consulted with state and local officials early in the process of developing the Clean Power Plan EGs to permit them to have meaningful and timely input into its development.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. There are no substantial costs imposed on tribes, and no actions taken that preempt tribal law. Thus, consultation under Executive Order 13175 is not required for this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA consulted with tribal officials during the development of this action. The EPA invited all tribes to government-to-government consultations and held consultations with the Forest County Potawatomi Indian Community, Navajo Nation, Ute Tribe of Uintah and Ouray Reservation, Blue Lake Rancheria and Gila River Indian Community. We also held technical and informational meetings with the Navajo Nation and the Ute Tribe of Uintah and Ouray Reservation. Additionally, the EPA held outreach and information workshops geared towards tribal audiences in Las Vegas, NV, Farmington, NM, and Tuba City, AZ.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not meet the definition in section 2–202.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The CEIP was finalized in the final Clean Power Plan, and this action provides design details for the program. The design details do not incorporate any provisions that are expected to have any adverse energy impacts.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action will not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples as specified in Executive Order 12898 (59 FR 7629; February 16, 1994) establishes federal executive policy on EJ. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make EJ part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. The EPA defines EJ as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.

The EPA has conducted extensive outreach and engagement with EJ and tribal communities as we have developed this proposed rule. Section V of this preamble, titled Community and Environmental Justice Considerations, provides details on the outreach and engagement efforts conducted. The goal of these efforts was two-fold: First, the Agency sought to provide EJ and tribal communities with background information on the CEIP; and second, the Agency sought input from both groups on key provisions of the program.

Whereas one priority of the CEIP is to overcome barriers to deployment of energy efficiency projects in low-income communities, thus, achieving emission reductions and providing compliance benefits to affected EGUs by providing these incentives in low-income communities, we believe that there will be considerable benefits provided to EJ and tribal communities. Our analysis indicates that by making the CEIP available to low-income populations, there is a significant segment of the population identified as minority, linguistically isolated, less than high school diploma, or under age 5 or over age 64 (factors typically considered when assessing EJ concerns), that are also potentially eligible to benefit from the CEIP. The full EJ analysis conducted for this proposal is summarized in section V of this preamble and details can be found in the document, *Environmental Justice Consideration for the Clean Energy Incentive Program (CEIP) Design Details,* located in the docket for this proposed rulemaking.

List of Subjects

40 CFR Part 60

Environmental protection, Administrative practices and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 62

Environmental protection, Administrative practices and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 16, 2016.

Gina McCarthy,

Administrator.

For the reasons stated in the preamble, title 40, chapter I, part 60 of the Code of Federal Regulations is proposed to be amended and title 40, chapter I, part 62 of the Code of the Federal Regulations, as proposed to be amended at 80 FR 64966, October 23, 2015, is proposed to be further amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 60.5737 is revised to read as follows:

§ 60.5373 What is the Clean Energy Incentive Program and how do I participate?

(a) This section establishes the Clean Energy Incentive Program (CEIP). Participation in this program is optional. Under the CEIP, States may allocate early action allowances or issue early action emission rate credits (ERCs) to projects in paragraphs (a)(1) and (2) of this section.

(1) Early action allowances or ERCs may be issued to Eligible CEIP renewable energy (RE) projects that generate electricity during calendar years 2020 or 2021.

(2) Early action allowances or ERCs may be issued to eligible CEIP low-income community projects that reduce electricity end-use or generate electricity and serve a low-income community during calendar years 2020 or 2021.

(b) For the CEIP the matching pool of allowances and ERCs for each State is specified in Tables 5 and 6 of this subpart.

(1) A State that participates in the CEIP, in accordance with the requirements of this section, will award on behalf of the EPA, matching allowances or ERCs, as applicable under its plan, from the State's apportioned matching allowances or ERCs specified in Tables 5 or 6 of subpart UUUU, as applicable.

(2) Each State's apportionment in tables 5 and 6 of this subpart is divided into a reserve of matching allowances or ERCs that may be awarded to eligible CEIP RE projects, and a reserve that may be awarded to eligible CEIP low-income community projects. Matching allowances or ERCs in each reserve may be awarded by a State on behalf of the EPA only for the eligible CEIP project type specified for the reserve.

(3) Any matching allowances or ERCs that are not awarded by January 1, 2023 will be retired by the EPA.

(c) If you participate in the CEIP, your plan must include the requirements in paragraphs (c)(1) through (10) of this section.

(1) Requirements that define the CEIP projects that will be eligible under your State's CEIP and that meet the requirements included in paragraphs (d) and (e) of this section.

(2) Requirements that restrict early action allowances to be allocated, or early action ERCs to be issued, only for electricity generation or savings achieved by eligible CEIP projects on or after January 1, 2020, and no later than December 31, 2021.

(3) Requirements for the process for the allocation of early action allowances, or the issuance of early action ERCs, to eligible CEIP projects that meet the requirements of § 60.5805 for ERC eligible resources.

(4) Requirements for a tracking system that meets the requirements of § 60.5810 in the case of a rate-based plan or § 60.5820 in the case of a mass-based plan.

(5) Requirements for EM&V plans that meet the requirements of § 60.5830.

(6) Requirements for monitoring and verification (M&V) reports that meet the requirements of § 60.5835.

(7) A mechanism that ensures that the issuance of early action allowances or ERCs would have no impact on the emission performance by affected EGUs required to meet rate-based or mass-based emission standards during the interim and final performance periods. Where a state issues early action ERCs, the mechanism must account for the issued early action ERCs on a one-for-one basis during the first step of the interim period.

(8) The definition(s) of "low-income community" you will apply to determine eligibility of CEIP low-income community projects. You must select a definition(s) that exists under a federal law, or under a state or local law in your state, or under a utility-administered program in your state, as of October 23, 2015. Routine updates of underlying federal, state or local data do not constitute a new definition for the purposes of this section.

(i) You may select different definitions for low-income community eligibility that consider geographic scale and/or different types of projects, but you must apply the selected definitions consistently across the State.

(ii) [Reserved]

(9) Requirements for recordkeeping and reporting that are consistent with the applicable requirements in § 60.5860(c) and (d). Where requirements at § 60.5860(c) refer to ERCs, such requirements must also apply, as applicable under your plan, to early action ERCs, matching ERCs, early action allowances, and matching allowances under the CEIP. Where requirements in § 60.5860(d) refer to ERCs or allowances, such requirements must also apply, as applicable under your plan, to early action ERCs, matching ERCs, early action allowances, and matching allowances under the CEIP.

(10) Your plan must not prohibit an eligible CEIP project from receiving early action ERCs or allowances on the basis that the project is located in Indian country.

(d) An RE project must meet the requirements in paragraphs (d)(1) through (4) of this section to be considered an eligible CEIP RE project.

(1) The project must be connected to and deliver energy to the electric grid in the contiguous United States.

(2) The project must either:

(i) Be located in a State participating in the CEIP, including Indian country within the borders of a State participating in the CEIP; or

(ii) Benefit a State participating in the CEIP or Indian country within the borders of a State participating in the CEIP.

(3) The project must commence commercial operation on or after January 1, 2020.

(4) The project must generate electricity from a wind, solar, geothermal, or hydropower RE resources, measured in MWh consistent with the requirements of 60.5830(c)(1).

(e) A low-income community demand-side EE project must meet the requirements of paragraphs (e)(1) through (5) of this section to be considered an eligible CEIP low-income community project. A low-income community renewable energy project must meet the requirements of paragraphs (e)(2) and (e)(5) through (8) of this section to be considered an eligible CEIP low-income community project.

(1) The project must save electricity in residences or buildings that are connected to the electric grid in the contiguous United States.

(2) The project must either:

(i) Be located in a State participating in the CEIP, including Indian country within the borders of a State participating in the CEIP; or

(ii) Benefit a State or Indian country within the borders of a State participating in the CEIP.

(3) The project must commence operation on or after September 6, 2018.

(4) The project must save electricity measured in MWh consistent with the requirements of § 60.5830(c)(2).

(5) The project must be implemented in a "low-income community" as defined in your plan for purposes of the CEIP and consistent with the requirements in paragraph (c)(8) of this section.

(6) The project must be connected to and deliver energy to the electric grid in the contiguous United States.

(7) The project must commence commercial operation on or after January 1, 2020.

(8) The project is a solar RE resource and is implemented to serve a low-income community, by providing direct electricity bill benefits to low-income community ratepayers. Such a project would be eligible for an award from the low-income community reserve of the matching pool for the energy generation that exclusively benefits low-income ratepayers, measured in MWh consistent with the requirements of § 60.5830(c)(1).

(f) Upon the EPA's approval of your plan that includes approved CEIP provisions, or upon promulgation of a federal plan for your State that includes the CEIP, the EPA will deposit your apportioned matching allowances or ERCs, as listed in tables 5 and 6 of subpart UUUU, into an account within your EPA-approved or EPA-administered tracking system. Following your allocation or issuance of early action allowances or ERCs to an eligible CEIP project provider, you must then award to the project provider matching allowances or ERCs on behalf of the EPA, according to paragraphs (f)(1) through (3) of this section.

(1) You must award matching allowances or ERCs on behalf of the EPA from your account no sooner than 60 days following State allocation or issuance of early action allowances or ERCs to a project provider.

(2) The EPA retains the authority to obtain documentation from you at any time to determine that your allocation of early action allowances or issuance of early action ERCs is in accordance with the requirements of this section.

(3) The EPA retains the authority to place a hold on your account, preventing the award of matching allowances or ERCs to an eligible CEIP project provider, if the EPA believes that you did not allocate early action allowances or issue early action ERCs in accordance with the requirements of this section.

(g) You must allocate early action allowances or issue early action ERCs, and you must award matching allowances or award matching ERCs on behalf of the EPA, according to paragraphs (g)(1) and (2) of this section.

(1) Allocation of early action allowances and award of matching allowances, is based on a 0.8 short ton of CO_2 per MWh factor, such that:

(i) For eligible CEIP RE projects, you must calculate early action allowances and matching allowances to be allocated and awarded to the project provider according to the following equations:

$$Early\ Action\ Allowances = 0.8({}^{short\ ton}/_{MWh}) \times \frac{MWh\ generated}{2}$$

$$Matching\ Allowances = 0.8({}^{short\ ton}/_{MWh}) \times \frac{MWh\ generated}{2}$$

Where:

Early Action Allowances = Allowances, denominated in short tons, allocated by the State rounded down to the nearest whole integer.

Matching Allowances = Allowances, denominated in short tons, awarded by the EPA rounded down to the nearest whole integer.

MWh generated = MWh generated by the eligible CEIP RE project.

(ii) For eligible CEIP low-income community projects, you must calculate early action allowances and matching allowances to be allocated and awarded to the project provider according to the following equations:

$$Early\ Action\ Allowances = 1.6({}^{short\ ton}/_{MWh}) \times \frac{MWh\ saved\ or\ generated}{2}$$

$$Matching\ Allowances = 1.6({}^{short\ ton}/_{MWh}) \times \frac{MWh\ saved\ or\ generated}{2}$$

Where:

Early Action Allowances = Allowances, denominated in short tons, allocated by the State rounded down to the nearest whole integer.

Matching Allowances = Allowances, denominated in short tons, awarded by the EPA rounded down to the nearest whole integer.

MWh saved or generated = MWh saved or generated by the eligible CEIP low-income project.

(2) Early action and matching ERCs will be issued and awarded such that:

(i) For every two MWh of electricity generated by an eligible CEIP RE project, you must issue one early action ERC to the project provider, and award on behalf of the EPA one matching ERC to the project provider.

(ii) For every two MWh in end-use electricity savings achieved by an eligible CEIP low-income community project, you must issue two early action ERCs to the project provider, and award on behalf of the EPA two matching ERCs to the project provider.

(3) A State may only allocate early action allowances from its established emission budget for the 2022–2024 interim step period.

(4) When awarding matching allowances or ERCs on behalf of the EPA, a State must assign a vintage for each awarded matching allowance or ERC that corresponds to the vintage of the related early action allowance or ERC on the basis of which the matching allowance or ERC was awarded.

(5) A State may only allocate or issue early action allowances or ERCs to eligible CEIP projects in a total amount not to exceed the number of matching allowances or ERCs apportioned to the State in Tables 5 or 6 of this subpart.

§ 60.5800 [Amended]

■ 3. Amend § 60.5800, paragraph (a) introductory text, by removing the text "ERCs" and adding the words "Except as provided in § 60.5737, ERCs" in its place.

§ 60.5815 [Amended]

■ 4. Amend § 60.5815 by removing and reserving paragraph (c).

■ 5. Amend § 60.5860 by revising paragraphs (d) introductory text and (d)(6) to read as follows:

§ 60.5860 What applicable monitoring, recordkeeping, and reporting requirements do I need to include in my plan for affected EGUs?

* * * * *

(d) Your plan must require the owner or operator of an affected EGU covered by your plan to include in a report submitted to you at the end of each compliance period the information in paragraphs (d)(1) through (6) of this section.

* * *

(6) If the owner or operator of an affected EGU is complying with an emission standard by using allowances, they must include in the report a list of all unique allowance serial numbers that were retired in the compliance period, and, for each allowance, the date an allowance was surrendered and retired.

* * * * *

■ 6. Amend § 60.5865 by adding paragraph (e) to read as follows:

§ 60.5865 What are my recordkeeping requirements?

* * * * *

(e) If your plan includes the CEIP, you must keep records of all information relied upon in support of any demonstration of CEIP requirements and supporting documentation, including records of all data submitted by a CEIP project provider, and submitted by the owner or operator of each affected EGU, that is used to determine compliance with each affected EGU emission standard or requirements in an approved State plan, consistent with the affected EGU requirements listed in § 60.5860. You must keep such records at a minimum for 10 years from the date the record is submitted to you. Each record must be in a form suitable and readily available for expeditious review.

■ 7. Amend § 60.5870 by revising paragraph (a) and adding paragraph (h) to read as follows:

§ 60.5870 What are my reporting and notification requirements?

(a) In lieu of the annual report required under § 60.25(e) and (f) of this part, you must report the information in paragraphs (b) through (f) and, if your plan includes the CEIP, (i) of this section.

* * * * *

(h) If your plan includes the CEIP, you must submit a report that includes the following information due no later than July 1, 2023: A list of all unique early action emission rate credit or early action allowance serial numbers that were issued or allocated by you for MWh from eligible CEIP projects from January 1, 2020 through December 31, 2021 (including all matching emission rate credit or allowance serial numbers) and identification information about each CEIP project sufficient to demonstrate that it is qualified to be issued or allocated such early action emission rate credits or early action allowances, and any other information specified in your plan.

■ 8. Section 60.5880 is amended by adding, in alphabetical order, the definitions for "Benefit a state", "Commence operation", "Commence commercial operation", "Early action allowance", "Early action emission rate credit or early action ERC", "Eligible CEIP project", "Eligible CEIP low-income community project", "Eligible CEIP renewable energy (RE) project", "Matching allowance", and "Matching emission rate credit or matching ERC" to read as follows:

§ 60.5880 What definitions apply to this subpart?

* * * * *

Benefit a state, for purposes of the CEIP, means that electricity is generated or saved by an eligible CEIP project with the intention to meet or reduce electricity demand in the CEIP participating State or Indian country located within the borders of the CEIP participating State.

* * * * *

Commence operation means, for the purposes of the CEIP, the date that a demand-side EE project is delivering quantifiable and verifiable electricity savings.

Commence commercial operation means, for the purposes of the CEIP, the date that a RE project begins to generate electricity for sale, including the sale of test generation, or to generate electricity that receives financial credit through net metering or equivalent policies.

* * * * *

Early action allowance means an allowance allocated by a state under the CEIP, in accordance with § 60.5737(c) through (e) and (g).

Early action emission rate credit or early action ERC means a tradable compliance instrument that meets the requirements of § 60.5790(c), except that, instead of meeting the requirements of § 60.5790(c)(2)(iii), it meets the requirements of § 60.5737(d) or (e) and is issued by a State or its agent through an EPA-approved ERC tracking system that meets the requirements of § 60.5790, or by the EPA through an EPA-administered tracking system.

Eligible CEIP project means a project that meets the requirements of § 60.5737(d) or (e). A "project," for purposes of the CEIP, may include a program that aggregates multiple projects.

Eligible CEIP low-income community project means a project that meets the requirements of § 60.5737(e). A "project," for purposes of the CEIP, may include a program that aggregates multiple projects.

Eligible CEIP renewable energy (RE) project means a project that meets the requirements of § 60.5737(d). A "project," for purposes of the CEIP, may include a program that aggregates multiple projects.

* * * * *

Matching allowance means an allowance awarded by the EPA, or by a State on behalf of the EPA, in accordance with 60.5737(f) through (g), based on the state allocation of an early action allowance under the CEIP.

Matching emission rate credit or matching ERC means an ERC awarded by the EPA, or by a State on behalf of the EPA, in accordance with § 60.5737(f) through (g), based on the state issuance of an early action ERC under the CEIP.

* * * * *

■ 9. Add Tables 5 and 6 to Subpart UUUU of part 60 to read as follows:

TABLE 5 TO SUBPART UUUU OF PART 60—STATE SHARES OF MATCHING POOL

[Allowances]

State/tribe	Available matching allowances (mass-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total share (100%)
Alabama	4,683,458	4,683,458	9,366,916
Arizona	2,579,426	2,579,426	5,158,852
Arkansas	3,280,844	3,280,844	6,561,688
California	328,268	328,268	656,536
Colorado	3,334,788	3,334,788	6,669,576
Connecticut	104,122	104,122	208,244
Delaware	207,588	207,588	415,176
Florida	4,845,372	4,845,372	9,690,744
Georgia	4,133,434	4,133,434	8,266,868
Idaho	22,392	22,392	44,784
Illinois	8,953,081	8,953,081	17,906,162
Indiana	8,631,114	8,631,114	17,262,228
Iowa	3,286,774	3,286,774	6,573,548
Kansas	3,173,445	3,173,445	6,346,890
Kentucky	7,429,292	7,429,292	14,858,584
Lands of the Fort Mojave Tribe	8,827	8,827	17,654
Lands of the Navajo Nation	2,434,598	2,434,598	4,869,196
Lands of the Uintah and Ouray Reservation	263,264	263,264	526,528
Louisiana	2,246,141	2,246,141	4,492,282
Maine	31,109	31,109	62,218
Maryland	1,459,162	1,459,162	2,918,324
Massachusetts	255,705	255,705	511,410
Michigan	5,591,791	5,591,791	11,183,582
Minnesota	3,004,354	3,004,354	6,008,708
Mississippi	535,959	535,959	1,071,918
Missouri	5,656,983	5,656,983	11,313,966
Montana	1,965,515	1,965,515	3,931,030
Nebraska	2,222,542	2,222,542	4,445,084
Nevada	504,431	504,431	1,008,862
New Hampshire	161,696	161,696	323,392
New Jersey	669,007	669,007	1,338,014
New Mexico	1,234,572	1,234,572	2,469,144
New York	836,656	836,656	1,673,312
North Carolina	4,011,884	4,011,884	8,023,768
North Dakota	3,225,953	3,225,953	6,451,906
Ohio	7,182,558	7,182,558	14,365,116
Oklahoma	3,100,508	3,100,508	6,201,016
Oregon	231,529	231,529	463,058
Pennsylvania	7,559,018	7,559,018	15,118,036
Rhode Island	53,511	53,511	107,022
South Carolina	2,479,202	2,479,202	4,958,404
South Dakota	396,310	396,310	792,620
Tennessee	3,267,125	3,267,125	6,534,250
Texas	15,600,288	15,600,288	31,200,576
Utah	2,101,783	2,101,783	4,203,566
Virginia	2,079,819	2,079,819	4,159,638
Washington	1,127,151	1,127,151	2,254,302
West Virginia	5,260,335	5,260,335	10,520,670
Wisconsin	3,590,805	3,590,805	7,181,610
Wyoming	4,656,486	4,656,486	9,312,972
Total	149,999,975	149,999,975	299,999,950

TABLE 6 TO SUBPART UUUU OF PART 60—STATE SHARES OF MATCHING POOL

[Emission rate credits]

State/tribe	Available matching ERCs (rate-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total share (100%)
Alabama	5,854,323	5,854,323	11,708,646
Arizona	3,224,283	3,224,283	6,448,566
Arkansas	4,101,055	4,101,055	8,202,110
California	410,335	410,335	820,670
Colorado	4,168,485	4,168,485	8,336,970
Connecticut	130,153	130,153	260,306
Delaware	259,485	259,485	518,970
Florida	6,056,715	6,056,715	12,113,430
Georgia	5,166,792	5,166,792	10,333,584
Idaho	27,991	27,991	55,982
Illinois	11,191,352	11,191,352	22,382,704
Indiana	10,788,892	10,788,892	21,577,784
Iowa	4,108,467	4,108,467	8,216,934
Kansas	3,966,806	3,966,806	7,933,612
Kentucky	9,286,616	9,286,616	18,573,232
Lands of the Fort Mojave Tribe	11,034	11,034	22,068
Lands of the Navajo Nation	3,043,247	3,043,247	6,086,494
Lands of the Uintah and Ouray Reservation	329,080	329,080	658,160
Louisiana	2,807,677	2,807,677	5,615,354
Maine	38,886	38,886	77,772
Maryland	1,823,952	1,823,952	3,647,904
Massachusetts	319,632	319,632	639,264
Michigan	6,989,739	6,989,739	13,979,478
Minnesota	3,755,443	3,755,443	7,510,886
Mississippi	669,949	669,949	1,339,898
Missouri	7,071,229	7,071,229	14,142,458
Montana	2,456,894	2,456,894	4,913,788
Nebraska	2,778,178	2,778,178	5,556,356
Nevada	630,539	630,539	1,261,078
New Hampshire	202,121	202,121	404,242
New Jersey	836,258	836,258	1,672,516
New Mexico	1,543,216	1,543,216	3,086,432
New York	1,045,820	1,045,820	2,091,640
North Carolina	5,014,855	5,014,855	10,029,710
North Dakota	4,032,441	4,032,441	8,064,882
Ohio	8,978,197	8,978,197	17,956,394
Oklahoma	3,875,635	3,875,635	7,751,270
Oregon	289,411	289,411	578,822
Pennsylvania	9,448,773	9,448,773	18,897,546
Rhode Island	66,889	66,889	133,778
South Carolina	3,099,003	3,099,003	6,198,006
South Dakota	495,387	495,387	990,774
Tennessee	4,083,907	4,083,907	8,167,814
Texas	19,500,360	19,500,360	39,000,720
Utah	2,627,229	2,627,229	5,254,458
Virginia	2,599,773	2,599,773	5,199,546
Washington	1,408,939	1,408,939	2,817,878
West Virginia	6,575,419	6,575,419	13,150,838
Wisconsin	4,488,506	4,488,506	8,977,012
Wyoming	5,820,607	5,820,607	11,641,214
Total	187,499,975	187,499,975	374,999,950

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 10. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart MMM—Greenhouse Gas Emissions Mass-Based Model Trading Rule for Electric Utility Generating Units That Commenced Construction on or Before January 8, 2014

■ 11. Revise § 62.16231, as proposed to be added at 80 FR 65062 (October 23, 2015), to read as follows:

§ 62.16231 How will the optional Clean Energy Incentive Program be administered?

(a) The CEIP will be administered according to the procedures in this section and those sections hereby cross-referenced in this section if the State elects to participate in the CEIP program. If the State does not elect to participate in the CEIP, the provisions included in this section and those sections hereby cross-referenced in this section, solely with respect to implementation of a CEIP program, shall not apply.

(b) The State will allocate early action allowances for electricity generation or savings achieved in the calendar years 2020 or 2021 to eligible CEIP projects that meet the requirements of § 62.16245 (c)(2) to be classified as an eligible CEIP RE project or eligible CEIP demand-side EE project.

(c) The State will allocate early action allowances to eligible CEIP projects up to the amounts specified for the Renewable Energy Reserve and the Low-Income Community Reserve, respectively, for the State in Table 4 of this subpart and pursuant to the requirements set forth in § 62.16235(e).

(d) The State will award matching allowances on behalf of the EPA from the State's account of matching allowances. Matching allowance awards will be made according to the ratio set forth in paragraph (e) of this section, and in an amount up to the amounts specified for the Renewable Energy Reserve and Low-Income Community Reserve, respectively, for the State as established in Table 5 of subpart UUUU of Part 60 of this chapter.

(e) The State will allocate early action allowances and award matching allowances on behalf of the EPA as follows. Allocation of early action allowances and award of matching allowances, is based on a 0.8 short ton of CO_2 per MWh factor, such that:

(1) For eligible CEIP RE projects, early action allowances and matching allowances to be allocated and awarded to the project provider will be calculated according to the following equations:

$$Early\ Action\ Allowances = 0.8({}^{short\ ton}/_{MWh}) \times \frac{MWh\ generated}{2}$$

$$Matching\ Allowances = 0.8({}^{short\ ton}/_{MWh}) \times \frac{MWh\ generated}{2}$$

Where:

Early Action Allowances = Allowances, denominated in short tons, allocated by the state rounded down to the nearest whole integer.

Matching Allowances = Allowances, denominated in short tons, awarded by the state on behalf of the EPA, rounded down to the nearest whole integer.

MWh generated = MWh generated by the eligible CEIP RE project.

(2) For eligible CEIP low-income community projects, the State will calculate early action allowances and matching allowances to be allocated and awarded to the project provider according to the following equations:

$$Early\ Action\ Allowances = 1.6({}^{short\ ton}/_{MWh}) \times \frac{MWh\ saved\ or\ generated}{2}$$

$$Matching\ Allowances = 1.6({}^{short\ ton}/_{MWh}) \times \frac{MWh\ saved\ or\ generated}{2}$$

Where:

Early Action Allowances = Allowances, denominated in short tons, allocated by the State rounded down to the nearest whole integer.

Matching Allowances = Allowances, denominated in short tons, awarded by the State on behalf of the EPA, rounded down to the nearest whole integer.

MWh saved or generated = MWh saved or generated by the CEIP low-income community project.

■ 12. Revise § 62.16235 paragraph (e) and Table 4, as proposed to be added at 80 FR 65063 (October 23, 2015), to read as follows:

§ 62.16235 What are the statewide mass-based emission goals, renewable energy set-asides, output-based set-asides, and Clean Energy Incentive Program early action set-asides?

* * * * *

(e) The state will set aside a portion of allowances for a Clean Energy Incentive Program Set-Aside covered under this subpart. The Clean Energy Incentive Program Set-Aside will contain the amount of allowances for the state shown in Table 4 of this section. Such amount will be reserved from the state's total emission budget for the first compliance period (2022–2024) as established in Table 1 of this subpart.

TABLE 4 TO SUBPART MMMM OF PART 62—CLEAN ENERGY INCENTIVE PROGRAM SET-ASIDE

[Allowances]

State/tribe	CEIP set-aside (mass-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total set-aside (100%)
Alabama	4,683,458	4,683,458	9,366,916
Arizona	2,579,426	2,579,426	5,158,852
Arkansas	3,280,844	3,280,844	6,561,688
California	328,268	328,268	656,536

TABLE 4 TO SUBPART MMMM OF PART 62—CLEAN ENERGY INCENTIVE PROGRAM SET-ASIDE—Continued
[Allowances]

State/tribe	CEIP set-aside (mass-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total set-aside (100%)
Colorado	3,334,788	3,334,788	6,669,576
Connecticut	104,122	104,122	208,244
Delaware	207,588	207,588	415,176
Florida	4,845,372	4,845,372	9,690,744
Georgia	4,133,434	4,133,434	8,266,868
Idaho	22,392	22,392	44,784
Illinois	8,953,081	8,953,081	17,906,162
Indiana	8,631,114	8,631,114	17,262,228
Iowa	3,286,774	3,286,774	6,573,548
Kansas	3,173,445	3,173,445	6,346,890
Kentucky	7,429,292	7,429,292	14,858,584
Lands of the Fort Mojave Tribe	8,827	8,827	17,654
Lands of the Navajo Nation	2,434,598	2,434,598	4,869,196
Lands of the Uintah and Ouray Reservation	263,264	263,264	526,528
Louisiana	2,246,141	2,246,141	4,492,282
Maine	31,109	31,109	62,218
Maryland	1,459,162	1,459,162	2,918,324
Massachusetts	255,705	255,705	511,410
Michigan	5,591,791	5,591,791	11,183,582
Minnesota	3,004,354	3,004,354	6,008,708
Mississippi	535,959	535,959	1,071,918
Missouri	5,656,983	5,656,983	11,313,966
Montana	1,965,515	1,965,515	3,931,030
Nebraska	2,222,542	2,222,542	4,445,084
Nevada	504,431	504,431	1,008,862
New Hampshire	161,696	161,696	323,392
New Jersey	669,007	669,007	1,338,014
New Mexico	1,234,572	1,234,572	2,469,144
New York	836,656	836,656	1,673,312
North Carolina	4,011,884	4,011,884	8,023,768
North Dakota	3,225,953	3,225,953	6,451,906
Ohio	7,182,558	7,182,558	14,365,116
Oklahoma	3,100,508	3,100,508	6,201,016
Oregon	231,529	231,529	463,058
Pennsylvania	7,559,018	7,559,018	15,118,036
Rhode Island	53,511	53,511	107,022
South Carolina	2,479,202	2,479,202	4,958,404
South Dakota	396,310	396,310	792,620
Tennessee	3,267,125	3,267,125	6,534,250
Texas	15,600,288	15,600,288	31,200,576
Utah	2,101,783	2,101,783	4,203,566
Virginia	2,079,819	2,079,819	4,159,638
Washington	1,127,151	1,127,151	2,254,302
West Virginia	5,260,335	5,260,335	10,520,670
Wisconsin	3,590,805	3,590,805	7,181,610
Wyoming	4,656,486	4,656,486	9,312,972
Total	149,999,975	149,999,975	299,999,950

■ 13. Amend § 62.16240 as proposed to be added at 80 FR 65067 (October 23, 2015), by adding paragraph (b)(3) to read as follows:

§ 62.16240 When are allowances allocated?

* * * * *

(b) * * *

(3) *Clean Energy Incentive Program set-aside.* By October 15, 2021 and October 15, 2022, the state will allocate allowances from the Clean Energy Incentive Program set-aside, based on quantified and verified MWh that occurred during the preceding calendar year, and will subsequently award matching allowances according to § 62.16245(c)(5).

* * * * *

■ 14. Amend § 62.16245 as proposed to be added at 80 FR 65068 (October 23, 2015), by adding paragraph (c) to read as follows:

§ 62.16245 How are set-aside allowances allocated?

* * * * *

(c)(1) *Clean Energy Incentive Program.* The State will establish a Clean Energy Incentive Program set-aside as set forth in § 62.16235(e), and allocate CO_2 allowances from the set-aside as outlined in this section.

(2) *Eligible CEIP projects.* To be eligible to receive allowances from the Clean Energy Incentive Program set-aside, and related EPA matching

allowances, an eligible CEIP project must meet the requirements in paragraphs (c)(2)(i) of this section for an eligible CEIP RE project and (c)(2)(ii) of this section for an eligible CEIP low-income community project. Any project that does not meet the applicable requirements of paragraphs (c)(2)(i) or (ii) of this section cannot receive allowances from the Clean Energy Incentive Program set-aside and related EPA matching allowances.

(i) An eligible CEIP RE project is a project that meets the requirements of paragraphs (c)(2)(i)(A) through (D) of this section.

(A) The project must be connected to and deliver energy to the electric grid in the contiguous United States.

(B) The project must either:

(1) Be located in a state participating in the CEIP, including Indian country within the borders of a State participating in the CEIP; or

(2) Benefit a state participating in the CEIP or Indian country within a state participating in the CEIP.

(C) The project must commence commercial operation on or after January 1, 2020.

(D) The project must generate electricity from a wind, solar, geothermal, or hydropower RE resources, measured in MWh consistent with the requirements of § 62.16260(c)(1) or (2) as applicable.

(ii) A low-income community demand-side EE project must meet the requirements of paragraphs (c)(2)(ii)(A) through (E) of this section to be considered an eligible CEIP low-income community project. A low-income community renewable energy project must meet the requirements of paragraphs (c)(2)(ii)(B) and (c)(2)(ii)(E) through (H) of this section to be considered an eligible CEIP low-income community project.

(A) The project must save electricity in residences or buildings that are connected to the electric grid in the contiguous United States.

(B) The project must either:

(1) Be located in a state participating in the CEIP, including Indian country within the borders of a state participating in the CEIP; or

(2) Benefit a state participating in the CEIP or Indian country within a state participating in the CEIP.

(C) The project must commence operation on or after September 6, 2018.

(D) The project must save electricity measured in MWh consistent with the requirements of § 62.16260(c)(7).

(E) The project must be implemented in a "low-income community" as defined under paragraph (c)(2)(iii) of this section.

(F) The project must be connected to and deliver energy to the electric grid in the contiguous United States.

(G) The project must commence commercial operation on or after January 1, 2020.

(H) The project is a solar RE resource and is implemented to serve a low-income community, by providing direct electricity bill benefits to low-income community ratepayers. Such a project would be eligible for an award from the low-income community reserve of the matching pool for the energy generation that exclusively benefits low-income ratepayers, measured in MWh consistent with the requirements of § 60.5830(c)(1) of this chapter.

(iii) For an eligible CEIP low-income community project, the project eligibility application must identify which one of the following definitions is used to establish the "low-income community" that the project will serve:

(A) The definition of low-income used by the New Market Tax Credit Program;

(B) The definition of low-income used by the Department of Housing and Urban Development's Qualified Census Tracts;

(C) The definition of low-income used by the Department of Energy's Weatherization Assistance Program Income Guidelines; or

(D) The definition of low-income used by the Federal Poverty Level Guidelines.

(3) *General account requirements.* In order to receive an allocation of allowances from the Clean Energy Incentive Program set-aside, the project provider must establish a general account in the tracking system as provided in § 62.16320(c).

(4) *Allocation of set-aside allowances.* The process and requirements for allocation of CEIP set-aside allowances, and the related award of EPA matching allowances are set forth in paragraphs (c)(4)(i) through (ii) of this section.

(i) *Eligibility application.* To receive set-aside allowances, and the related award of EPA matching allowances, the authorized account representative of an eligible CEIP project must submit an eligibility application to the state that demonstrates that the requirements of paragraph (c)(2) of this section are met and includes the following information:

(A) Identification of the authorized account representative of the eligible CEIP project, including the authorized account representative's name, address, email address, telephone number, and allowance tracking system account number;

(B) Project identification information under paragraph (a)(3)(i)(B) of this section, to the extent applicable, and information demonstrating that the project meets the criteria of paragraph (c)(2) of this section, and paragraph (a)(2)(v) of this section;

(C) Certification required under paragraph (a)(3)(ii)(C) of this section;

(D) An EM&V plan required under paragraph (a)(3)(ii)(D) of this section that meets the requirements of § 62.16260;

(E) Verification report from an accredited independent verifier who meets the requirements of § 62.16275 and § 62.16280 and that meets the requirements of paragraph (a)(3)(ii)(E) of this section and § 62.16270.

(F) The authorization under paragraph (a)(3)(ii)(F) of this section;

(G) The statement required under paragraph (a)(3)(ii)(G) of this section.

(ii) *Monitoring and Verification Report.* To receive set-aside allowances, and the related award of EPA matching allowances, following the year in which the electricity generation or savings occurred, the authorized account representative must submit to the state the monitoring and verification information required under paragraph (a)(4) of this section that meets the requirements of § 62.16265. A monitoring and verification report must be submitted to the state by no later than September 15 of the applicable calendar year.

(5) *Allocation of Clean Energy Incentive Program allowances.* Upon the state's approval of the monitoring and verification information submitted for an eligible CEIP project, the State will transfer allowances from the CEIP set-aside into the general account for the authorized account representative of the eligible CEIP project. Allowances will only be allocated from the CEIP set-aside based on quantified and verified electricity generation or savings from an eligible CEIP project that occurred on or after January 1, 2020, and no later than December 31, 2021. No earlier than 60 days from the date of the allocation of allowances from the CEIP set-aside, the state will award matching allowances on behalf of the EPA. The state will transfer matching allowances from the state's account of matching allowances into the general account for the authorized account representative of the eligible CEIP project, in accordance with § 62.16231(e). Matching allowances awarded will be assigned the same allowance vintage as the related early action allowances that were allocated by the state. Early action allowances will not be allocated, and matching allowances will not be awarded, on the basis of a monitoring and verification report submitted after September 15, 2022. Any matching allowances that are

not awarded by January 1, 2023, will be retired by the state on behalf of the EPA.

(6) *Revocation of qualification status of an eligible CEIP project.* The process for revocation of qualification status under § 62.16250 applies to eligible CEIP projects.

(7) *Error adjustments or misstatements, and suspension of allowance issuance.* The process for error adjustments or misstatement, and suspension of allowance issuance under § 62.16255 applies to eligible CEIP projects.

(8) *Recordkeeping and Reporting Requirements.* The reporting and recordkeeping requirements for the owner or operator of an affected EGU under § 62.16360(a)(1)(vi) and 62.16365(a)(2)(iv), respectively, that apply to the use for compliance of set-aside allowances also apply to allowances that were allocated from the Clean Energy Incentive Program set-aside and the related matching allowances that were awarded by the State on behalf of the EPA.

■ 15. Amend § 62.16375, as proposed to be added at 80 FR 65085 (October 23, 2015), by adding, in alphabetical order, the definitions for "Benefit a state", "Commence operation", "Commence commercial operation", "Early action allowance", "Eligible CEIP project", "Eligible CEIP low-income community project", "Eligible CEIP renewable energy (RE) project", and "Matching allowance" to read as follows:

§ 62.16375 What definitions apply to this subpart?

* * * * *

Benefit a state, for purposes of the CEIP, has the same meaning as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Commence operation, for purposes of the CEIP, has the same meaning as defined in subpart UUUU of part 60 of this chapter.

Commence commercial operation, for purposes of the CEIP, has the same meaning as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Early action allowance has the same meaning as defined in subpart UUUU of part 60 of this chapter.

Eligible CEIP project has the same meaning as defined in subpart UUUU of part 60 of this chapter.

Eligible CEIP low-income community project has the same meaning as defined in subpart UUUU of part 60 of this chapter.

Eligible CEIP renewable energy (RE) project has the same meaning as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Matching allowance has the same meaning as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Subpart NNN—Greenhouse Gas Emissions Rate-Based Model Trading Rule for Electric Utility Generating Units That Commenced Construction on or Before January 8, 2014

■ 16. Revise § 62.16431, as proposed to be added at 80 FR 65092 (October 23, 2015), to read as follows:

§ 62.16431 How will the optional Clean Energy Incentive Program be administered?

(a) The Clean Energy Incentive Program (CEIP) will be administered according to the procedures in this section and those sections hereby cross-referenced in this section if the State elects to participate in the CEIP. If the state does not elect to participate in the CEIP, the provisions included in this section and those sections hereby cross-referenced in this section, solely with respect to implementation of a CEIP, shall not apply.

(b) The state will issue early action ERCs for electricity generation or savings achieved in the calendar years 2020 or 2021 to eligible CEIP projects that meet the requirements of § 62.16435 (d) to be classified as an eligible CEIP RE project or an eligible CEIP low-income community project.

(c) The state will issue early action ERCs to eligible CEIP projects up to the amounts specified for the Renewable Energy Reserve and the Low-Income Reserve, respectively, for the State in Table 4 of this subpart and pursuant to the requirements set forth in this section.

(d) The state will award matching ERCs on behalf of the EPA from the State's account of matching ERCs. Matching ERC awards will be made according to the ratio set forth in paragraph (e) of this section, and in an amount up to the amounts specified for the Renewable Energy Reserve and Low-Income Reserve, respectively, for the state as established in Table 6 of subpart UUUU of Part 60 of this chapter.

(e) The issuance of early action ERCs by the state, and the award of matching ERCs by the state on behalf of the EPA, will be executed according to paragraphs (e)(1) and (2) of this section.

(1) For eligible CEIP RE projects that generate metered MWh of electricity: For every two MWh generated, the project will receive one early action ERC and one matching ERC.

(2) For eligible CEIP low-income community projects: For every two MWh in end-use electricity savings achieved or for every two MWh of electricity generated, the project will receive two early action ERCs and two matching ERCs.

(f) The process for ERC issuance provided in § 62.16445, the requirements for evaluation, measurement, and verification in § 62.16455, the requirements for monitoring and verification reports in § 62.16460, the requirements for independent verifiers in §§ 62.16470 through 62.16480, and the requirements for verification reports in § 62.16465, shall apply to the issuance of early action ERCs to eligible CEIP projects and shall also be the basis for the award of matching ERCs to eligible CEIP projects.

(1) The process for revocation of qualification status under § 62.16440 shall apply.

(2) The process for error adjustments or misstatement, and suspension of ERC issuance under § 62.16450 shall apply.

(3) The reporting requirements of § 62.16555 and the recordkeeping requirements of § 62.16560 shall apply with respect to both early action ERCs issued by the state and matching ERCs awarded by the state on behalf of the EPA.

TABLE 1 TO § 62.16431—CLEAN ENERGY INCENTIVE PROGRAM EARLY ACTION EMISSION RATE CREDITS

State/tribe	Available early action ERCs (rate-based plan states)		
	Renewable energy reserve (50%)	Low-income community reserve (50%)	Total early action ERCs (100%)
Alabama	5,854,323	5,854,323	11,708,646
Arizona	3,224,283	3,224,283	6,448,566
Arkansas	4,101,055	4,101,055	8,202,110
California	410,335	410,335	820,670
Colorado	4,168,485	4,168,485	8,336,970
Connecticut	130,153	130,153	260,306
Delaware	259,485	259,485	518,970
Florida	6,056,715	6,056,715	12,113,430
Georgia	5,166,792	5,166,792	10,333,584
Idaho	27,991	27,991	55,982
Illinois	11,191,352	11,191,352	22,382,704
Indiana	10,788,892	10,788,892	21,577,784
Iowa	4,108,467	4,108,467	8,216,934
Kansas	3,966,806	3,966,806	7,933,612
Kentucky	9,286,616	9,286,616	18,573,232
Lands of the Fort Mojave Tribe	11,034	11,034	22,068
Lands of the Navajo Nation	3,043,247	3,043,247	6,086,494
Lands of the Uintah and Ouray Reservation	329,080	329,080	658,160
Louisiana	2,807,677	2,807,677	5,615,354
Maine	38,886	38,886	77,772
Maryland	1,823,952	1,823,952	3,647,904
Massachusetts	319,632	319,632	639,264
Michigan	6,989,739	6,989,739	13,979,478
Minnesota	3,755,443	3,755,443	7,510,886
Mississippi	669,949	669,949	1,339,898
Missouri	7,071,229	7,071,229	14,142,458
Montana	2,456,894	2,456,894	4,913,788
Nebraska	2,778,178	2,778,178	5,556,356
Nevada	630,539	630,539	1,261,078
New Hampshire	202,121	202,121	404,242
New Jersey	836,258	836,258	1,672,516
New Mexico	1,543,216	1,543,216	3,086,432
New York	1,045,820	1,045,820	2,091,640
North Carolina	5,014,855	5,014,855	10,029,710
North Dakota	4,032,441	4,032,441	8,064,882
Ohio	8,978,197	8,978,197	17,956,394
Oklahoma	3,875,635	3,875,635	7,751,270
Oregon	289,411	289,411	578,822
Pennsylvania	9,448,773	9,448,773	18,897,546
Rhode Island	66,889	66,889	133,778
South Carolina	3,099,003	3,099,003	6,198,006
South Dakota	495,387	495,387	990,774
Tennessee	4,083,907	4,083,907	8,167,814
Texas	19,500,360	19,500,360	39,000,720
Utah	2,627,229	2,627,229	5,254,458
Virginia	2,599,773	2,599,773	5,199,546
Washington	1,408,939	1,408,939	2,817,878
West Virginia	6,575,419	6,575,419	13,150,838
Wisconsin	4,488,506	4,488,506	8,977,012
Wyoming	5,820,607	5,820,607	11,641,214
Totals	187,499,975	187,499,975	374,999,950

(g) To account for the State issuance of early action ERCs to eligible CEIP projects, the quantified and verified MWh from any eligible resource during the first interim step period (2022 through 2024) that are the basis for the issuance of ERCs will be adjusted according to paragraphs (g)(1) and (2) of this section.

(1) Quantified and verified MWh reported by an eligible resource will be multiplied by an adjustment factor calculated in accordance with paragraph (g)(2) of this section. When applying the adjustment factor, the calculated number of MWh for which ERCs may be issued by the State is rounded down to the nearest integer.

(2) The adjustment factor will be determined by the following equation:

$$\text{Adjustment Factor} = 1 - \frac{\text{State Issued Early Action ERCs} / \text{Adjustment Period}}{\text{Quantified \& Verified MWh During Reporting Year}}$$

Where:

State-Issued Early Action ERCs = the total number of early action ERCs issued by the state under the CEIP

Adjustment Period = 3, the number of years during the first interim step of the interim performance period

Quantified and Verified MWh During Reporting Year = The total number of quantified and verified MWh reported by all eligible resources that occurred during a respective year during the first interim step period

■ 17. Amend § 62.16435, as proposed to be added at 80 FR 65093 (October 23, 2015), by adding paragraph (d) to read as follows:

§ 62.16435 What eligible resources qualify for generation of ERCs in addition to affected EGUs?

* * * * *

(d)(1) If a State chooses to establish a CEIP under § 62.16431, then eligible CEIP projects are those that meet the requirements of paragraph (d)(2) of this section.

(2) To be eligible to receive early action ERCs from the CEIP, and related EPA matching ERCs, an eligible CEIP project must meet the requirements in paragraph (d)(2)(i) of this section for an eligible CEIP RE project and paragraph (d)(2)(ii) of this section for an eligible CEIP low-income community project. Any project that does not meet the applicable requirements of paragraphs (d)(2)(i) or (ii) of this section cannot be issued early action ERCs and awarded related EPA matching ERCs.

(i) An eligible CEIP RE project is a project that meets the requirements or paragraphs (d)(2)(i)(A) through (D) of this section.

(A) The project must be connected to and deliver energy to the electric grid in the contiguous United States.

(B) The project must either:

(1) Be located in a State participating in the CEIP, including Indian country within the borders of a state participating in the CEIP; or

(2) Benefit a state participating in the CEIP or Indian country within a State participating in the CEIP.

(C) The project must commence commercial operation on or after January 1, 2020.

(D) The project must generate electricity from a wind, solar, geothermal, or hydropower RE resources, measured in MWh consistent with the requirements of § 62.16455(c)(1) or (2), as applicable.

(ii) A low-income community demand-side EE project must meet the requirements of paragraphs (d)(2)(ii)(A) through (E) of this section to be considered an eligible CEIP low-income community project. A low-income community renewable energy project must meet the requirements of paragraphs (d)(2)(ii)(B) and (d)(2)(ii)(E) through (H) of this section to be considered an eligible CEIP low-income community project.

(A) The project must save electricity in residences or buildings that are connected to the electric grid in the contiguous United States.

(B) The project must either:

(1) Be located in a state participating in the CEIP, including Indian country within the borders of a State participating in the CEIP; or

(2) Benefit a state participating in the CEIP or Indian country within a state participating in the CEIP.

(C) The project must commence operation on or after September 6, 2018.

(D) The project must save electricity measured in MWh consistent with the requirements of § 62.16455(c)(7).

(E) The project must be implemented in a "low-income community" as defined under paragraph (d)(2)(iii) of this section.

(F) The project must be connected to and deliver energy to the electric grid in the contiguous United States.

(G) The project must commence commercial operation on or after January 1, 2020.

(H) The project is a solar RE resource and is implemented to serve a low-income community, by providing direct electricity bill benefits to low-income community ratepayers. Such a project would be eligible for an award from the low-income community reserve of the matching pool for the energy generation that exclusively benefits low-income ratepayers, measured in MWh consistent with the requirements of § 60.5830(c)(1) of this chapter.

(iii) For an eligible CEIP low-income community project the project eligibility application must identify which one of the following definitions is used to establish the "low-income community" that the project will serve:

(A) The definition of low-income used by the New Market Tax Credit Program;

(B) The definition of low-income used by the Department of Housing and Urban Development's Qualified Census Tracts;

(C) The definition of low-income used by the Department of Energy's Weatherization Assistance Program Income Guidelines; or

(D) The definition of low-income used by the Federal Poverty Level Guidelines.

■ 18. Amend § 62.16445, as proposed to be added at 80 FR 65094 (October 23, 2015), by adding paragraph (g) to read as follows:

§ 62.16445 What is the process for issuance of ERCs?

* * * * *

(g) *Clean Energy Incentive Program early action ERCs.* Upon the state's approval of the monitoring and verification information submitted for an eligible CEIP project, the state will issue early action ERCs, and transfer those early action ERCs into the general account for the authorized account representative of the eligible CEIP project. Early action ERCs will only be issued based on quantified and verified electricity generation or savings from an eligible CEIP project that occurred on or after January 1, 2020, and no later than December 31, 2021. No earlier than 60 days from the date of the issuance of early action ERCs, the state will award matching ERCs on behalf of the EPA. The state will transfer matching ERCs from the State's account of matching ERCs into the general account for the authorized account representative of the eligible CEIP project, in accordance with § 62.16431(d) and (e). Early action ERCs will not be issued, and matching ERCs will not be awarded, on the basis of a monitoring and verification report submitted after September 15, 2022. Any matching ERCs that are not awarded by January 1, 2023, will be retired by the state on behalf of the EPA.

■ 19. Amend § 62.16570, as proposed to be added at 80 FR 65110 (October 23, 2015), by adding, in alphabetical order, definitions for "Benefit a state", "Commence operation", "Commence commercial operation", "Early action emission rate credit or early action ERC", "Eligible CEIP project", "Eligible CEIP low-income community project", "Eligible CEIP RE project", and "Matching emission rate credit or matching ERC" to read as follows:

§ 62.16375 What definitions apply to this subpart?

* * * * *

Benefit a state, for purposes of the CEIP, has the same meaning as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Commence operation, for purposes of the CEIP, means the definition as defined in subpart UUUU of part 60 of this chapter.

Commence commercial operation, for purposes of the CEIP, means the definition as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Early action emission rate credit or early action ERC means the definition as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Eligible CEIP project means the definition as defined in subpart UUUU of part 60 of this chapter.

Eligible CEIP low-income community project means the definition as defined in subpart UUUU of part 60 of this chapter.

Eligible CEIP renewable energy (RE) project means the definition as defined in subpart UUUU of part 60 of this chapter.

* * * * *

Matching emission rate credit or matching ERC means the definition as defined in subpart UUUU of part 60 of this chapter.

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[FR Doc. 2016–15000 Filed 6–29–16; 8:45 am]

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Thursday, June 30, 2016

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